INTRAPARTUM FETAL MONITORING AND PERINATAL OUTCOME

A dissertation submitted in partial fulfillment of the requirements of the Tamil Nadu Dr M.G.R Medical University for the degree of MS (Obstetrics and Gynecology) examination to be held in May 2018

DECLARATION CERTIFICATE

I hereby declare that this dissertation titled "INTRAPARTUM FETAL MONITORING AND PERINATAL OUTCOME" is carried out by me under the guidance and supervision of Dr Annie Regi, Professor and Head of Unit III, Obstetrics and Gynecology, Christian Medical College, Vellore.

This dissertation is submitted in partial fulfillment of the requirements of the Tamil Nadu Dr M.G.R Medical University for the degree of MS (Obstetrics and Gynecology) examination to be held in May 2018.

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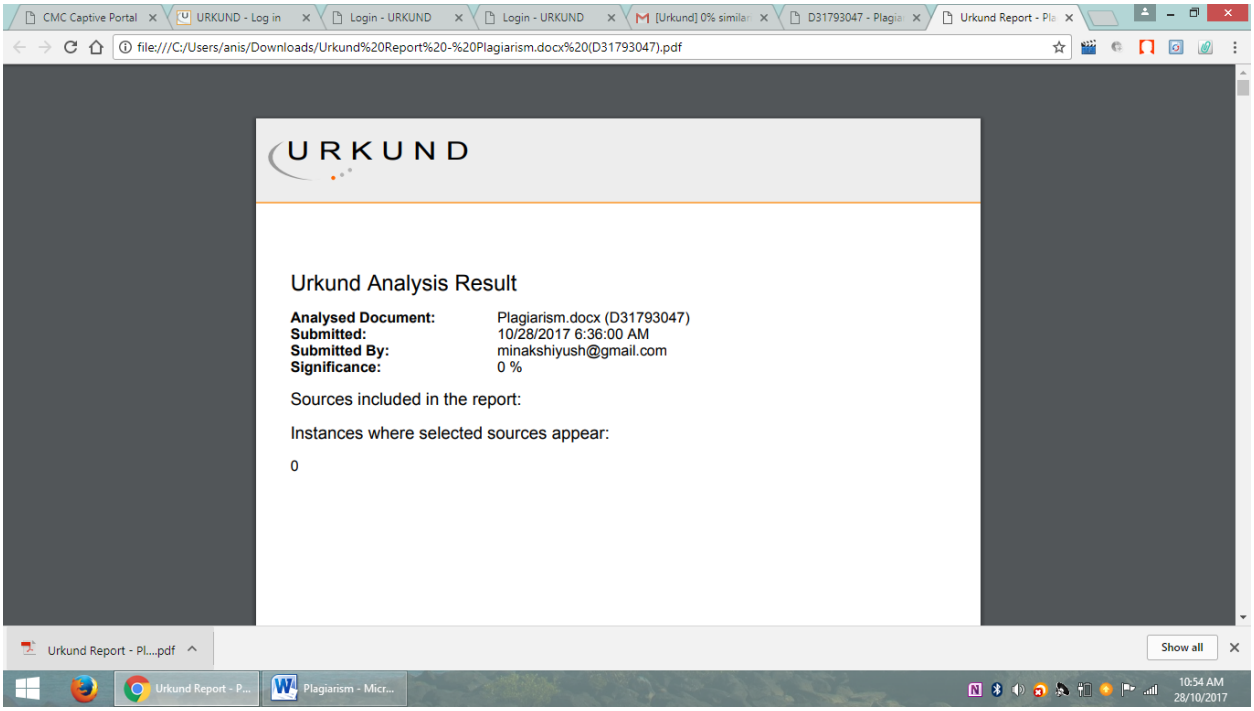
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ABBREVIATION

- ACOG : American College of Obstetrics and Gynecology
- ANS : Autonomic Nervous System
- BHR : Baseline Heart Rate
- BPM : Beats Per Minute
- BPP : Bio-physical Profile
- CNGOF: French College of Gynecology and Obstetrics
- CO2 : Carbon dioxide
- CTG : Continuous Cardiotocography
- EFM : Electronic Fetal Monitoring
- FGR : Fetal Growth Restriction
- FHR : Fetal Heart Rate
- FIGO : International Federation of Gynecology and Obstetrics
- HIE : Hypoxic Ischemic Encephalopathy
- HELLP : Hemolysis Elevated Liver Enzymes Low Platelet
- MSAF : Meconium Stained Amniotic Fluid
- NICE : National Institute of Clinical Excellence
- NICHD : National Institute of Child Health and Human Development
- NICU : Neonatal Intensive Care Unit
- NST : Non Stress Test
- PNS : Parasympathetic Nervous System

- RCT : Randomized Control Trial
- SIRS : Systemic Inflammatory Response Syndrome
- USA : United States of America

CONTENTS

INTRODUCTION

Optimizing maternal, infant and child health is a major public health goal worldwide and is particularly of importance in developing countries like India. The well-being of mothers and their babies during the course of pregnancy and labour is a strong determinant of the health of the next generation. When maternal and fetal surveillance continues into infancy, public health challenges for families and communities in the future can be successfully predicted and prevention strategies planned.

A wide spectrum of clinical methods and investigations are available for surveillance of the intra-uterine fetus in the womb, which may be initiated from early pregnancy right up to birth. These range from the use of traditional equipment like the Pinard's fetoscope or a stethoscope to auscultate the fetal heart, maternal fetal movement/kick count and fetal biophysical profile (BPP) and modified BPP by ultrasound, to intrapartum electronic fetal monitoring and scalp blood sampling which gives functional information about the unborn child. BPP constitutes real time ultrasound and Non Stress Test (NST) (Table 1). For NST negative predictive value is 99.8% and for BPP and modified BPP it is 99.9%(1). Nageotte et al described modified BPP which constitutes NST and Amniotic Fluid Index (AFI). Here NST is a short term indicator of fetal oxygen status and AFI is long term marker of placental perfusion status(2).

Table1. Biophysical Profile Scoring System

NST[a]	Reactive: 2 Points Nonreactive: 0 Points	Management
Fetal breathing movement	At least one episode of breathing movement for 30 s: 2 points	10 out of 10 or 8 out of 10→ normal test
Fetal movement	3 or more discrete body movements: 2 points	6 out of 10→ equivocal test, should be repeated within 24 h
Fetal tone	1 or more flexion/extension movements of extremity or hand: 2 points	4 out of 10→ abnormal test, should prompt delivery if >32 wk; if <32 wk, individualize based on provider judgment
Amniotic fluid volume	Deepest vertical pocket of at least 2 cm: 2 points	2 out of 10→ abnormal test, deliver immediately

Close monitoring of the fetal heart rate and patterns in labour is essential, as labour can be a state of progressive acidemia. Maternal efforts of bearing down increases the intra-abdominal pressure and repeated contractions increase the intrauterine pressure, which occasionally exceed the pressure of placental perfusion. This in turn causes intermittent fetal hypoxia, repeated episodes of which, gradually result in fetal acidemia (3).

The purpose of intrapartum fetal surveillance is to diagnose abnormalities in fetal heart rate and pick up fetal acidemia before it becomes irreversible. Fetal hypoxia in labour causes ischemic encephalopathy (HIE) and in severe cases, irreversible brain injury. Greater degrees of ischemia may lead to seizures, cerebral palsy and mental retardation (4). Hence, the purpose of intrapartum fetal monitoring is to enable timely delivery before irreversible brain tissue injury occurs.

Intrapartum fetal surveillance can be done either by intermittent auscultation or

continuous electronic fetal heart rate monitoring using the cardiotocography (CTG). CTG traces are interpreted according to the three tier fetal heart rate interpretation system recommended by 2008 National Institute of Child Health and Human Development NICHD workshop - Category I (Normal), Category II (Indeterminate) and category III (Abnormal) (5)(Table 2).

Prior studies have showed no significant difference in the neonatal outcome with some increase in the Caesarean section rates. But in the busy labour room where the monitoring by auscultation is impractical, it has provided the convenience of monitoring. The limitation of continuous EFM is high false positives, which means even if the trace seems to be abnormal, actually the fetus would not be hypoxic(6). Several studies have been done on the reproducibility of the electronic fetal monitoring. The results have shown poor inter- and intra-observer consistency. A meta-analysis done by Thacker et al. compared the newborn seizure rate between continuous EFM and intermittent auscultation group. It showed no significant difference in the neonatal seizure rate. Another fact was that the newborn with cerebral palsy belonged to the CTG patterns which were not ominous (4).

Table2. NICHD Three Tier Classification (2008)

Category I

- Category I FHR tracings include all of the following:
- Baseline rate: 110–160 beats per minute
- Baseline FHR variability: moderate
- Late or variable decelerations: absent
- Early decelerations: present or absent
- Accelerations: present or absent

Category II

Category II FHR tracings includes all FHR tracings not categorized as Category I or Category III. Category II tracings may represent an appreciable fraction of those encountered in clinical care. Examples of Category II FHR tracings include any of the following:

Baseline rate

- Bradycardia not accompanied by absent baseline variability
- Tachycardia

Baseline FHR variability

- Minimal baseline variability
- Absent baseline variability with no recurrent decelerations
- Marked baseline variability

Accelerations

- Absence of induced accelerations after fetal stimulation

Periodic or episodic decelerations

- Recurrent variable decelerations accompanied by minimal or moderate baseline variability
- Prolonged deceleration more than 2 minutes but less than10 minutes
- Recurrent late decelerations with moderate baseline variability
- Variable decelerations with other characteristics such as slow return to baseline, overshoots, or "shoulders"

Category III

Category III FHR tracings include either

- Absent baseline FHR variability and any of the following:
  - –Recurrent late decelerations
  - –Recurrent variable decelerations
  - –Bradycardia
- Sinusoidal pattern

Another method to detect intrapartum fetal hypoxia is scalp blood sampling. In 1960, Saling had introduced intrapartum fetal scalp blood sampling for determination of blood pH as an indicator of fetal hypoxia(7). Fetal scalp blood pH is considered to be the gold standard for detection of intrapartum hypoxia and acidemia. However, in the developing countries like ours , practically scalp blood sampling is not feasible(8).

In a limited resource setting like ours we do intrapartum resuscitative measures like, stopping the oxytocin infusion, putting the mother in left lateral recumbent position, hydration, amnioinfusion in case of recurrent variable decelerations etc. In case of category III traces immediate delivery is done. By performing this study we would like to evaluate the CTG patterns that are truly non-reassuring which is translated as neonatal depression at birth.

Newborn depression at birth will be identified by Apgar <7 at 5 min, abnormal breathing requiring Positive Pressure Ventilation, cord pH <7.2, base excess >12mmol/L, NICU admission and development of encephalopathy. We would also like to evaluate if these abnormal CTG patterns lead to any instrumental delivery or caesarean section in the mother.

AIMS AND OBJECTIVES

Aim: To identify the intrapartum fetal heart rate patterns associated with increased risk of neonatal depression using cardiotocography (CTG).

Objectives:

(I)To identify the intrapartum abnormal fetal heart rate patterns using Cardiotocography and categorize according to the NICHD 3-tier classification

(II)To identify the CTG patterns associated with increased risk of neonatal depression

(III) To evaluate the route of delivery among these women who had an abnormal CTG trace

REVIEW OF LITERATURE

Introduction

Cord compression in labour has varying effect on fetal oxygen distribution to the various organs. With fifty percent decrease of blood flow in the umbilical vessels the cardiac output is increased in brain, heart, kidneys and gastrointestinal tract whereas blood flow to liver reduces by 75%(9). Severe uterine contractions in labor which occurs mainly in second stage reduces the blood flow to the uterus due to increased vascular resistance. Birth asphyxia is due to poor gas exchange and is characterized by three biochemical changes; hypercapnia, hypoxemia and metabolic acidosis(10). Perinatal asphyxia i.e., deprivement of oxygen at delivery, is defined postnatally as blood pH <7, base deficit <-12, Apgar score <5 at 5 minutes, neuroimaging showing cortical injury at watershed areas, multiorgan failure, and cerebral palsy(11). Hence it is a retrospective diagnosis. Intrapartum it can only be predicted that a baby might have birth asphyxia depending upon the CTG trace category II or III. The perinatal asphyxia leads to hypoxic ischemia to different organs. It causes organ damage depending upon the degree of insult ranging from neonatal death, to life-long diseases. Hypoxic ischemia is the secondary to birth asphyxia which is associated with other organ

damage. Mild damage might lead to subtle brain disorders such as attention deficit hyperactive disorder, schizophrenia or lifelong psychiatric disorders. Whereas severe damage causes developmental delay, epileptic disorders, mental retardation, neurodegenerative diseases etc. (12). The prime objective of fetal monitoring during labour is to recognize fetuses which are going to develop hypoxia and in turn to expedite delivery before irreversible tissue injury occurs.

The fetal monitoring during labour can be done by various methods viz. intermittent auscultation, continuous cardiotocography, colour of amniotic fluid, quantity of amniotic fluid and fetal scalp blood sampling. In an update forwarded by Alfirevic et al. it was concluded that intrapartum use of CTG has been related with lower rates of seizures in neonates but there is no obvious differences in occurrence of cerebral palsy. On the other hand there was higher rate of operative vaginal deliveries and Caesarean sections associated with continuous CTG(13). Fetal monitoring during labour using electronic monitor was developed in 1960s in order to prevent fetal hypoxia. By 1970s, it became the standard of care in most of the countries and by 2002, over 85% labours have been monitored using electronic monitor across the world(14).

Auscultatory method Verses Electronic Monitoring

Studies have shown that monitoring with intermittent auscultatory method using

stethoscopes as effective as the continuous cardiotocography. The Dublin trial which was a RCT , compared continuous electronic monitoring with intermittent auscultation included around 13000 labouring mothers. The Caesarean rates were 2.2% and 2.4% in continuous monitoring and intermittent auscultation respectively. The rates of operative vaginal delivery were 6.3% and 8.4%.The small difference in Caesarean rate is due to detection of low scalp blood pH for patients on electronic monitor. Though there was no difference in NICU admission for probable asphyxia, low Apgar and acidosis(15). Another randomized study also showed no remarkable difference in immediate perinatal outcome. It was concluded that the practicality of intermittent auscultation is comparable to continuous monitoring and safe in low risk labouring women(16). In a randomized controlled trial where the Doppler auscultation was compared with CTG at admission in low risk mothers there was not any remarkable differences in the occurrences of acidosis or other adverse neonatal outcome. However it was shown to increase the chances of interventions like operative vaginal births(17). Devane D et al forwarded an update including four trials accounting 13000 labouring women conducted in Ireland and United Kingdom. It showed women allotted to admission CTG had more rate of requirement of continuous monitoring and requirement of unnecessary fetal scalp sampling in comparison to no admission CTG. The secondary outcome studied was incidence and stages of ischemic encephalopathy and occurrence of neonatal seizures where the data did not differ much. In fact it suggested that likelihood of Caesarean is increased by 20% with the use of admission CTG(18). CTG has got high sensitivity but less specificity(19).That means even if the CTG pattern shows

abnormality , the neonate would not have any hypoxia or acidosis. It has been seen that a few CTG patterns has association with brain injury leading to cerebral palsy. These patterns are late decelerations that's the deceleration occurs after the peak of uterine contraction. It signifies the utero-placental insufficiency that leads to hypoxia and in turn brain injury. But again high false positivity is associated with these trace findings. And ultimately all these lead to increased Caesarean section and rate of operative vaginal deliveries(20). According to a prospective study by Sultana et al,

for predicting abnormal outcomes, sensitivity and specificity of the CTG was found to be 87% and 66% respectively, positive and negative predictive value were 54% and 92% respectively. And it was concluded that if the CTG is normal it will predict the good outcomes and on the other hand abnormal CTGs might not predict the adverse outcomes(21).

The second objective of this intrapartum monitoring is to prevent unwarranted interventions like Caesarean sections or instrumental deliveries. All these interventions causes maternal morbidities viz. urinary tract infections, pain, wound infections, postpartum hemorrhage in turn leading to transfusion related problems, peritonitis, lactation failure, financial problems etc.

The normal CTG pattern indicates that the fetus is getting oxygen well. Though almost fifty percent of patterns signal that there is some abnormality or fetus is hypoxic. However in reality very less number of fetuses develop hypoxia requiring resuscitation(7,22). In 1962 Saling had instigated the fetal scalp blood sampling for determination of pH as a marker of hypoxia. Later the studies have done comparison

between blood pH and lactates for accuracy of determining fetal hypoxia. The results have been comparable(7). Some studies have shown greater sensitivity and specificity for scalp blood lactate measurement as a determinant of fetal condition.

Epidemiology

The prevalence of perinatal asphyxia depends upon the socio – economic state, education and profession of parents and demography. Asphyxia can be antenatal or intrapartum. Maternal infections viz. chorioamnionitis, multiple gestation, prematurity increases the risk of prenatal asphyxia. On the other hand hypoxia during process of parturition is the most important cause of perinatal hypoxia(23).

The Global Burden of Disease study had obtained a statistical data from year 2000 – 2002, showed overall number of deaths including all age groups of 56 million per year globally. Out of it, 10.5 million (20%) is among less than 5 years children. In this group the foremost causes of death were found to be related to perinatal complications(24). A study in USA showed 60 % death in children was linked to perinatal complications including birth asphyxia(25).The biggest data has been collected by developing country. Almost 1/3rd of neonatal death worldwide had been reported from India.

The most common causes of death in newborns is summarized in following figure which is for Tamilnadu (Fig 1)(23).

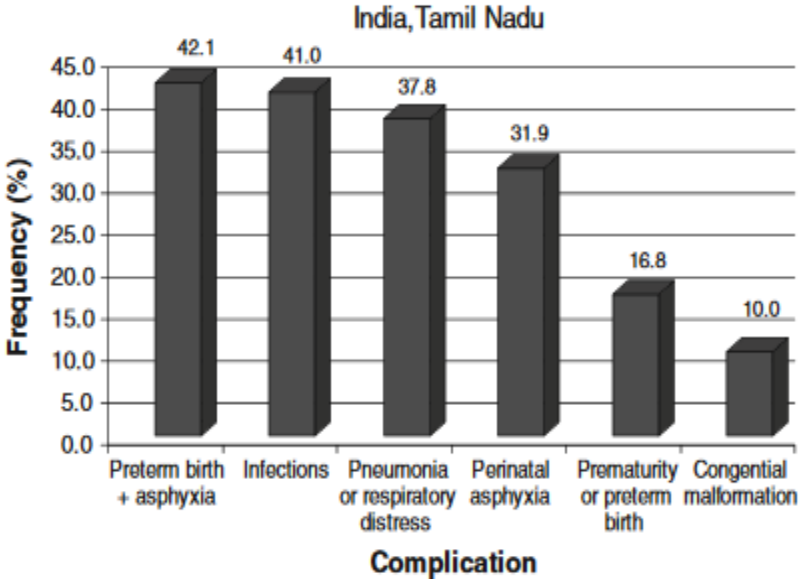


Fig 1.Birth Asphyxia and preterm birth most common cause for perinatal mortality

A study done in ten Inter-mount Health Care, hospitals and study period was between March 2007 –June 2009. It included the singleton pregnancy in cephalic presentation more than or equal to thirty seven weeks. The result showed the occurrence of different categories of CTG traces intra-partum is as follows: category I in 80%, category II in 22% and category III in 0.004%(26). Hence the category three patterns is rare. A prospective study done which included over 170 primigravidas including both high and low risk pregnancies. 13% of low risk became high risk due abnormal CTG changes in early labour.

No statistical difference in baseline fetal heart rate and variability between the high and low risk pregnancies. However the decelerations are more common in high risk

patients(27). In a prospective study for period of 5 years (March 2002 to March 2007) done in a tertiary center where 3148 labouring mothers >36 weeks gestational age were included. All these having continuous electronic monitoring for fetal heart, 6.8% were taken for caesarean section for non-reassuring status of fetuses. Here the persistent bradycardia was found to be the commonest abnormal fetal heart pattern that is 48.8% next common being late decelerations (17.8%) followed by poor variability (7.5%) (28). A retrospective study done at a Teaching Hospital in Nigeria, for a period of seven years. This study included over 17000 deliveries, concluded that the clinical diagnosis of intrapartum fetal distress is almost accurate in 29.1% cases(29).

Definitions and Terminology

The main goal of fetal monitoring during labour is for prevention of untoward perinatal outcomes secondary to cerebral hypoxia or metabolic acidosis associated with labour. Fetal monitoring during labour can help in detecting various problems like hypoxia, tachycardia, cord compression, placental abruption, acidosis etc. The understanding of various fetal heart rate and patterns enable the obstetricians to take resuscitative measures. However there are many other factors which actually lead to evolution and severity of asphyxia and related injury. Asphyxia is a condition of impaired gas exchange, which when persistent, leads to progressive hypoxemia, hypercapnia, and metabolic acidosis(30).

There are certain background risk factors which should be considered while monitoring the labouring mother and during the interpretation of CTG trace (18).The various factors can be divided into three categories viz. maternal, utero-placental and fetal factors (Table 2).

Table2. Risk Factors for Increased Chances of Fetal Acidemia

Maternal factors	Decreased maternal arterial oxygen tension
	respiratory disease
	hypoventilation, seizure, trauma
	smoking
	Decreased maternal oxygen carrying capability
	significant anemia (e.g., iron deficiency, hemoglobinopathies)
	carboxyhemoglobin (smokers)
	Decreased uterine blood flow
	hypotension (e.g., blood loss, sepsis)
	regional anaesthesia
	maternal positioning
	Chronic maternal conditions
	vasculopathies (e.g., systemic lupus erythematosus, type I diabetes, chronic hyper-tension)
	antiphospholipid syndrome
Fetal factors	Cord compression
	oligohydramnios
	cord prolapse or entanglement
	Decreased fetal oxygen carrying capability
	significant anaemia (e.g., isoimmunization, maternal-fetal bleed, ruptured vasa previa)
	Carboxyhemoglobin (if mother is a smoker)

Recommendations for Fetal Surveillance

The percentage of continuous fetal monitoring has been increased by the implementation of CTG at admission. Also the Caesarean have increased but it might identify the small percentage of at risk fetus which were left unrecognized (Level I).Women which are low risk can be equally benefitted by intermittent auscultation and it is an appropriate method for them (Level I). Electronic fetal monitoring is recommended for women with high risk pregnancies who are at risk for fetal compromise (II-A) .When there are recognized risk factors which can lead to fetal compromise either detected antenatally, at the labour onset or develop intrapartum, the continuous electronic fetal monitoring with CTG has been recommended(Level I)(31). However there are various indications for electronic continuous fetal monitoring during labor where this monitoring is strictly recommended (Table 3). The electronic monitoring can be intervened for thirty minutes in case the patient is in early labour with normal CTG, the rate of oxytocin infusion is constant and the condition of mother and fetus is stable(33,34).Too much of uterine contractions in the form of either tachysystole or hypertonus, the continuous CTG is recommended (Consensus based).The presence of hyperstimulation is also an indication for continuous CTG (Consensus based).Tocolysis is recommended and injection Terbutaline is the drug of choice(Level I)(35).

There is a consensus based recommendation which says that the centres equipped with electronic monitors for intrapartum monitoring should have the access for fetal scalp blood sampling to see whether the CTG changes are equivocal. It is recommended to assess lactates rather than pH(Level I)(36).

Table 3:Indications for Continuous Electronic Intra-partum Monitoring(14,34)

Antenatal and intrapartum factors that increase risk of fetal compromise. Intrapartum cardiotocography is recommended	
Antenatal risk factors	**Intrapartum risk factors**
• abnormal antenatal CTG • abnormal Doppler umbilical artery velocimetry • suspected or confirmed intrauterine growth restriction • oligohydramnios or polyhydramnios • prolonged pregnancy ≥ 42 weeks[22] • multiple pregnancy[23] • breech presentation[24, 25] • antepartum haemorrhage • prolonged rupture of membranes (≥ 24 hours)[24] • known fetal abnormality which requires monitoring • uterine scar (e.g. previous caesarean section) • essential hypertension or pre-eclampsia • diabetes where medication is indicated[26] or poorly controlled, or with fetal macrosomia • other current or previous obstetric or medical conditions which constitute a significant risk of fetal compromise (e.g. cholestasis, isoimmunisation, substance abuse) • fetal movements reduced (within the week preceding labour)[102,103] • morbid obesity (BMI ≥ 40)[27, 28] • maternal age ≥ 42[29-31] • abnormalities of maternal serum screening associated with an increased risk of poor perinatal outcomes (e.g. low	• induction of labour with prostaglandin/oxytocin • abnormal auscultation or CTG • oxytocin augmentation • regional anaesthesia (e.g. epidural or spinal)* and paracervical block • abnormal vaginal bleeding in labour • maternal pyrexia ≥ 38°C[33] • meconium or blood stained liquor [34] • absent liquor following amniotomy • prolonged first stage as defined by referral guidelines • prolonged second stage as defined by referral guidelines • pre-term labour less than 37 completed weeks • tachysystole (more than five active labour contractions in ten minutes, without fetal heart rate abnormalities) • uterine hypertonus (contractions lasting more than two minutes in duration or contractions occurring within 60 seconds of each other, without fetal heart rate abnormalities) • uterine hyperstimulation (either tachysystole or uterine hypertonus with fetal heart rate abnormalities).

Most important indications for continuous fetal monitoring during labour being; (a) the pregnancy with high probability of cerebral palsy, perinatal asphyxia or encephalopathy which are restricted fetal growth, hypertension, multiple pregnancies, placental abruption, prematurity, chorioamnionitis, post maturity etc.(b) labour which is either induced or augmented with oxytocin, (c) postdated pregnancy(37).

CTG Interpretation

The first objective of this study is to identify the abnormal CTG patterns. Hence it is important to know the proper interpretation of CTG trace. There are various guidelines for interpretation of CTG. The features which should be mentioned during CTG trace readings are; baseline heart, characteristic of variability, accelerations present or not, and deceleration whether present or not .If the deceleration is present then the kind and severity of deceleration. As recommended by NICE each feature of CTG has to be categorized as “abnormal”, “reassuring” and “non-reassuring”(Table 4).Also the CTG should be classified as “pathological”, ”suspicious” and “normal”(Table 5)(32,38). Along with the fetal heart reading the toco part of it should be analysed. It is equally important as the intensity of uterine contractility also affects the CTG pattern. It may give the hint of the underlying reason for the abnormal pattern of CTG and hence guide further management. The various grades of contractions, whether it is tachysystole, hyperstimulation or loss of contractions would give the idea of next plan of action.

Table4. Characterization of CTG as per NICE guidelines

Feature	Baseline (bpm)	Variability (bpm)	Decelerations	Accelerations
Reassuring	110–160	≥ 5	None	Present
Non-reassuring	100–109 161–180	< 5 for 40–90 minutes	Typical variable decelerations with over 50% of contractions occurring for over 90 minutes Single prolonged deceleration for up to 3 minutes	The absence of accelerations with otherwise normal trace is of uncertain significance
Abnormal	< 100 > 180 Sinusoidal pattern ≥ 10 minutes	< 5 for 90 minutes	Either atypical variable decelerations with over 50% of contractions or late decelerations, both for over 30 minutes Single prolonged deceleration for more than 3 minutes	

Table5. NICE classification of CTG

Category	Definition
Normal	A CTG where all four features fall into the 'reassuring' category
Suspicious	A CTG where one of the features falls into 'non-reassuring category' and the remainder of the features are reassuring
Pathological	A CTG whose features fall into two or more non-reassuring categories or one or more abnormal categories

Is it also of utmost importance to consider the underlying maternal and fetal risk factors such as presence of maternal pyrexia, hypertensive disorders (eclampsia, pre-eclampsia, HELLP syndrome etc.), renal disease, patient undergoing trial of labour after Caesarean section, oxytocin augmentation, post term pregnancy, history of antepartum hemorrhage, prolonged rupture of membranes, woman with suspected cephalo - pelvic disproportion.

Fetal risk factors being, fetal growth restriction, oligohydramnios, multiple pregnancies, meconium stained liquor, prematurity, fetus with cardiac disorder or any other congenital anomaly, presence of chorioamnionitis etc. These underlying risk factors might increase the likelihood of perinatal asphyxia.

FIGO Classification System for Intrapartum Cardiotocography(39)

FIGO Classification System for Intrapartum Monitoring (2015)

	Normal CTG[a]	Suspicious CTG	Pathological CTG
Baseline[b]	110-160 bpm	Lacking at least one of normal characteristics, but with no pathological features	<100 bpm
Variability[c,d,j]	5-25 bpm		Reduced/increased variability[c,d]; sinusoidal pattern[j]
Decelerations[e,f,g,h,i]	No repetitive* decelerations		Repetitive* late or prolonged decelerations for >30 min (or >20 min if reduced variability); one deceleration >5 min
Interpretation	No hypoxia/acidosis	Low probability of hypoxia/acidosis	High probability of hypoxia/acidosis

*Decelerations are called as repetitive when it occurs with more than fifty percent of the uterine contractions.

a) In this system of CTG classification, accelerations have been excluded because the absence of acceleration in a trace has undetermined significance, however presence of it is an indicator of neurologically healthy fetus with absence of any hypoxia or acidosis.

b) Fetal heart rate >160 beats per minute and <110 beats per minute is defined as fetal tachycardia and bradycardia respectively if it occurs for >10 minutes duration.

c) Appearance of bandwidth <5 bpm for a time period >50 minutes in a baseline segment and during decelerations for >3 minutes is defined as decreased variability.

d) Bandwidth >25 bpm for a period of >30 minutes is defined as increased variability, also called saltatory pattern.

e) Fall in fetal heart rate by >15 bpm for a time period >15 seconds is called deceleration.

f) The decelerations coinciding with contractions, having normal beta to beat variability, short lasting and shallow are early.

g) An abrupt drop of fetal heart rate to nadir in 30 seconds after starting of uterine contraction but with good variability and quick return to the baseline are variable decelerations.

h) Late decelerations are characterized by; onset of deceleration >20 seconds after the start of contractions, gradual onset over >30 seconds, reach nadir after peak of contraction with gradual return to baseline from nadir in >30 seconds.

i) Decelerations lasting >3 minutes are called prolonged.

j) Smooth, regular and undulating pattern similar to sinus wave, amplitude of 5 to 15 bpm, 3-5 cycles/min of frequency for time period >30 minutes are sinusoidal pattern this also coincides with absence of accelerations.

Classification system updated by National Institute of Child Health and Human Development (NICHD) in association with Society of Maternal Fetal Medicine and American College of Obstetrics and Gynecologists (table 7):

Table 7.The Three - Tier Fetal Heart Rate Classification System

Category I

Category I fetal heart rate patterns include all of the following:

Baseline rate of 110–160 beats per minute
Moderate baseline fetal heart rate variability
Late or variable decelerations are absent
Early decelerations may be present or absent
Accelerations may be present or absent

Category II

Category II fetal heart rate tracings include all patterns not categorized as category I or category III

Category III

Category III fetal heart rate patterns include:

Absent baseline fetal heart rate variability with any of the following:
- Recurrent late decelerations
- Recurrent variable decelerations
- Bradycardia

Sinusoidal pattern

Describing Normal CTG

When all four features of a CTG are within reassuring category of the classification, the CTG is called as normal(Figure 2). It should fulfill the following norm; i) stable baseline fetal heart rate falling between 110-160 bpm ii) Variability between 5-25 bpm oscillating from above to below the baseline iii) The "cycling activity" of the fetus should be there i.e., alternating periods of decreased fetal heart variability and elevated variability where the accelerations may or may not present. Unlike antenatally where the accelerations should be present in the CTG to call it normal it is acceptable to have absent

accelerations intrapartum in the presence of other reassuring features. The cycling activity is the basic characteristic of the fetus that is non-hypoxic. It indicates that fetal cardiovascular and neurological systems are intact enough to defend against the insults of process of parturition. Also it symbolizes the good physical condition of fetus and normoxia(40). The probability of fetal compromise is very low. Despite the normal CTG having a poor perinatal outcome can occur when the underlying cause is other than hypoxia such as prematurity, maternal fever, congenital anomalies or metabolic problems in newborn. On the other hand sometimes CTG at a point is categorized as reassuring but there is neurological injury perinatally. This can be the scenario when the changes in baseline heart rate and variability is missed hence it is crucial to have an idea of the entire trace rather than a small segment. Features when present in isolation are unlikely to have adverse perinatal outcome are; absent accelerations, presence of early decelerations, baseline heart rate between 100-109 bpm and presence of variable decelerations in the absence of complicating features (Good practice notes)(34).

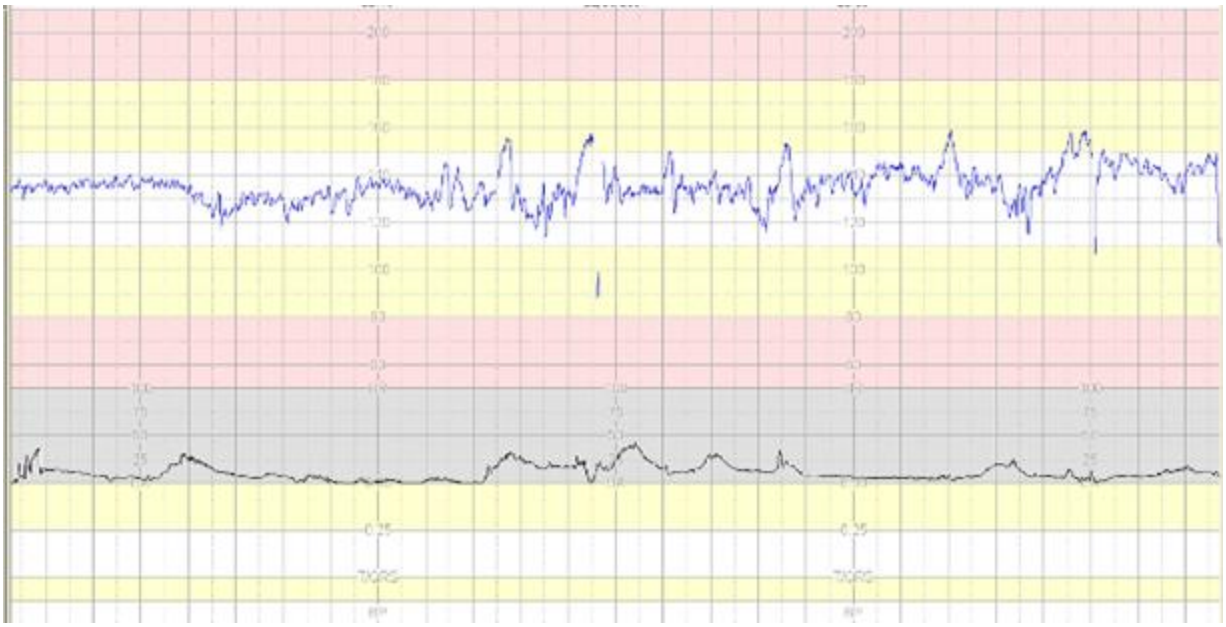


Figure2. Showing normal CTG with BHR 130-140 bpm, good variabilty, presence of accelerations.

Considering underlying Clinical Situation

It is important to be aware of the clinical background when the CTG is being interpreted by an obstetrician .These are as follows, the stage of labor, uterine contractions and its intensity, capability of fetus to cope up with further hypoxia, prematurity, meconium stained liquor, physiological reserves, antepartum hemorrhage, intrapartum fever, fetal growth restriction, chorioamnionitis.

Beat to beat Variability

The fetal variability can be described as the random ups and downs in baseline and are irregular in frequency and amplitude. This shift is generated by sudden but normal variations in the recess between successive fetal heart beats. To express normal variability the integrity of cerebral cortex, vagus nerve, midbrain, and conductive tissues

of heart is essential. Fetus with CTG showing normal variability is found to be at low risk of brain injury or impending death due to asphyxia. This is regardless of presence of any bradycardia or decelerations(41).Cycling activity is the basic conduct of a neurologically sound and non-hypoxic fetus which are term or close to term. It is said that normal or increased beat to beat variability should alternate with a period of reduced variability which is an indicator of normal cycling activity. And if there is no such cyclical variation it is a matter of concern. One should think about the underlying causal factors such as; fetal hypoxia, exposure to drugs (e.g., sedatives, oxytocin, narcotics, magnesium sulphate, atropine etc.), intrauterine infections, neural tube defect such as anencephaly, brain hemorrhage in fetus, complete heart blockade(42). Hence the diminished or no variability is described to be a very important sign of hypoxia in fetus and ongoing acidemia in term as well as preterm fetuses(43,44). It has been suggested by a systematic review that most accurate prediction of neonatal acidemia can be done with CTG showing very minimal or undetectable variability. This type of variability in association with late / variable decelerations is even more consistent indicator, 23% association. Also it was reported that moderate variability had strong association with good outcomes in terms of cord pH >7.15 and Apgar at 5 minutes more than or equal to 7 (45).The fetal heart variability >25 bpm is also called as ‘saltatory pattern’ is thought to be associated with evolving hypoxia (Figure 3).The presence of such feature in existing variable or late decelerations should be taken as abnormal. The physiology is autonomic nervous system tries to maintain the stable heart rate during the time of fastly progressing

hypoxia(46)

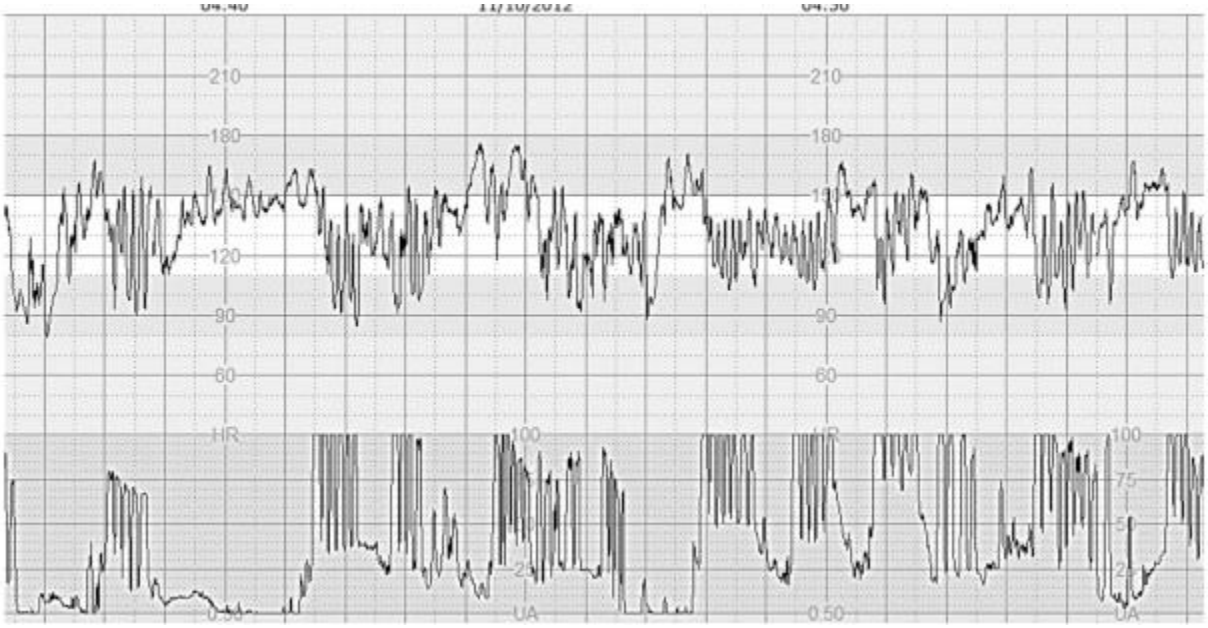


Figure 3. shows Saltatory pattern, indicator of fastly evolving hypoxia, generally due to injudicious use of oxytocin.

The inferences which can be drawn from above stated discussion are: (i) sporadic or persistent decrease in fetal heart variability in combination to deceleration can be the indicator of decompensation unless intrapartum asphyxia is ruled out. (ii) In the absence of any process of intervening asphyxia causing fetal heart decelerations, it is very unlikely to appear poor variability in previously normal CTG with normal variability. (iii) It is almost impossible to differentiate the cause of poor variability whether asphyxia or not without doing fetal blood sampling if poor variability is there from starting of the monitoring itself.

Variation in Baseline Heart Rate in Fetus

The different baseline changes are fetal tachycardia, bradycardia or indefinite heart rate.

The tachycardia in preterm fetuses may be physiological because of immature parasympathetic system. Other physiological reasons are maternal fever, drugs like betamimetics, or maternal dehydration. Fetal tachycardia secondary to maternal fever can be due to intrauterine infection e.g., chorioamnionitis. Chorioamnionitis may lead to systemic inflammation. There can be generalized endothelial injury as part of SIRS, this in turn is linked with hypotension, low Apgar, seizures, depression at birth, meconium aspiration, HIE, periventricular leucomalacia, intraventricular hemorrhage and cerebral palsy(47–50). At present electronic monitoring lacks sensitivity to identify the inflammatory response in fetus and inflammation in placenta or anticipate neonatal sepsis. Rise in fetal heart rate can be an indicator of fetal hypoxia. It may be due to utero-placental insufficiency. Here fetus attempts to increase cardiac output by increasing heart rate in order to supply blood to the vital organs. Baseline fetal tachycardia if associated with other ominous features, such as poor variability or deceleration is called “complicated tachycardia”.

Fetal bradycardia i.e., decrease in heart rate <110/min, in association with normal beat to beat variability, accelerations and absence of decelerations can be physiological in post term pregnancy. To call it baseline bradycardia the heart rate should remain at this baseline for minimum 10 minutes. On the other hand the decrease in baseline <80 bpm transiently is termed as “prolonged deceleration”. If the duration of this deceleration is <3 minutes, it is suspicious and if it is >3 minutes it is abnormal. It indicates that there is high probability of rapidly growing fetal hypoxia.

Fetal Heart Decelerations : There are three categories of decelerations. **Early**

decelerations are also called as “mirror image” .It was first explained by Hon and Quilligan and later by Caldeyro- Barcia. These are secondary to fetal head compression this in turn causes stimulation of parasympathetic nervous system. **Late decelerations** are the indicator of utero – placental insufficiency hence it is ominous. These are moderated via chemo – receptors in the fetus which are stimulated secondary to fetal hypercarbia, hypoxemia and acidosis. If the CTG shows late deceleration along with poor or absent variability it designates pre-terminal trace and immediate delivery should be expedited. **Variable decelerations** are the most common decelerations found intrapartum.

These decelerations vary in timing, shape and form in correlation to uterine contractions. The “typical” ones are associated with ‘shouldering, duration of occurrence is <60 seconds and fall from the baseline is also <60 bpm. In the presence of normal variability and baseline these are not worrisome. This is seen during cord compression in absence of acidosis. The physiology is selective occlusion of umbilical vein stimulates baroreceptors this in turn increases the fetal heart rate. Here though the fetus gets lesser amount of blood from the placenta but maintains the cardiac output by increasing heart rate in the presence of hypovolemia and hypotension. This is an uncomplicated type of variable deceleration (Figure 4).

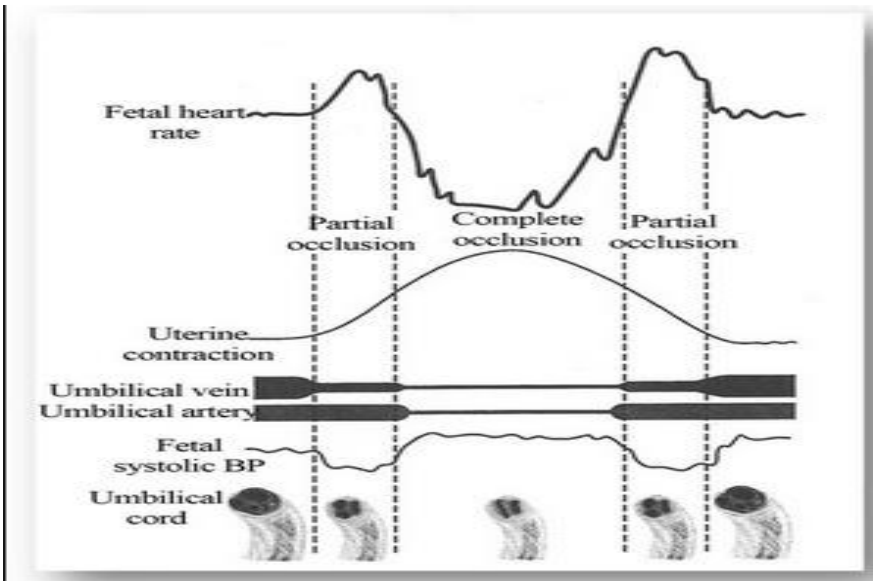


Figure4: Showing uncomplicated variable deceleration

The “atypical” lasts for >60 seconds and falls below baseline for >60 bpm. This is followed by overshoots. This occurs due to complete blocking of the cord. This indicates under way fetal hypotension due to complete and prolonged obstruction of cord. Again the physiology is baroreceptor – chemoreceptor driven (Figure 5).

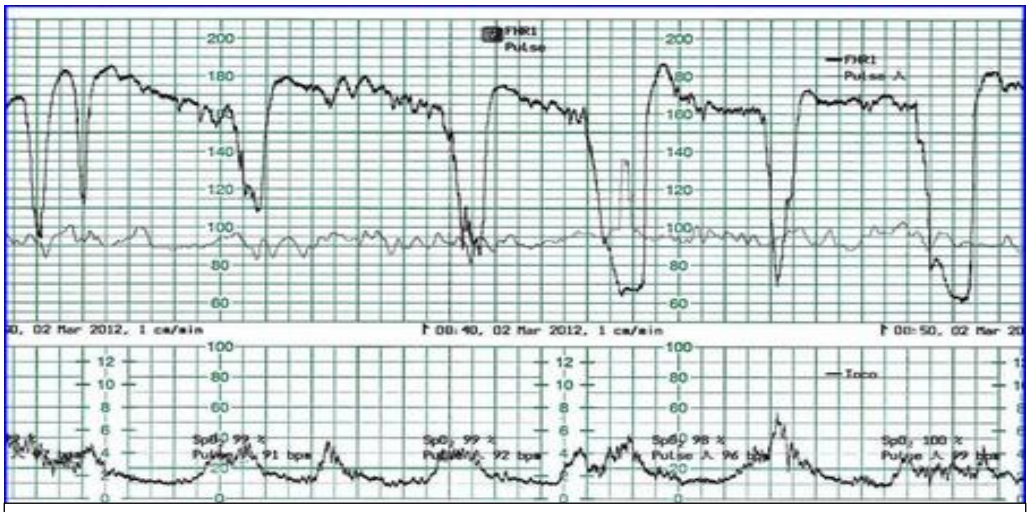


Fig.5 Recurrent variable decelerations followed by overshoots

However if the CTG shows stable and normal baseline along with normal variability with the presence of decelerations, risk of acidosis is found to be low. Even the duration and type of decelerations also doesn't influence much(51,52).

Intrapartum Fetal Pathophysiology

The understanding of the fetal response for stress during parturition is the integral part of CTG interpretation. The goal is, identifying fetuses which are not able to cope up through evolving hypoxia using own compensatory mechanism. It is vital to have understanding of normal physiology of fetus during labor in order to interpret the changes on CTG trace correctly. Also it is crucial to know that each and every fetus have different stamina and reserves to behave towards the same ongoing hypoxia and mechanical stress. A term and good size baby has more effective compensatory mechanism than the preterm or a FGR baby(53).The speed of evolving hypoxia is also equally important to build the compensatory response for preventing intrapartum hypoxic-ischemia. The other factors which should be always considered in the management are presence of chorioamnionitis, MSAF, maternal infection, oligo or anhydramnios etc. Regulation of the heart rate in fetus is carried out by the autonomic and the somatic nervous system. Therefore the presence of accelerations which in turn are due to active fetal movements indicate the normally functioning somatic system. On the other hand the accelerations disappears when fetus reduces the nonessential activities for energy conservation, if fetus is experiencing any hypoxia.

The fetal heart variability is maintained by the equilibrium between ANS and PNS. The presence of good oxygenation and good functioning brain centres are reflected by the presence of good variability. The early deceleration is due to head compression. There are rich supply of vagus nerve at the duramater which in turn activates parasympathetic system during head compression. There is no constituent of hypoxia here.

The late decelerations are due to uterine-placental insufficiency where there is collection of carbon dioxide and lactic acid. Here due to deficiency of oxygen the anaerobic metabolism is activated in place of aerobic leading to metabolic acidosis. The CO2 and hydrogen ions stimulate the chemoreceptors in the aortic and carotid bodies and also in brain. As a fetal compensatory response the heart rate decreases. The well oxygenated blood tries to wash off the accumulated carbon dioxide and acid which slowly releases the stimulus on the chemoreceptors and hence leading to slowly recovering heart rate to the normal baseline(51,52).

The fetal tachycardia can be pathological and the sign of evolving hypoxia. As a protective mechanism fetus releases catecholamine that is adrenaline and nor-adrenaline from adrenals which causes increase in heart rate(54).The other causes that alter the fetal heart rate are maternal (fever, dehydration, hypovolemia or tachycardia), medications (opioids, betamimetics), fetal (arrhythmias, infection, cardiac anomalies) or vaginal examination that is mechanical cause.

Types of Intrapartum Hypoxia

The understanding of the process of hypoxia and the fetal adaptation to it which is reflected by the changes on the CTG is imperative to guide the timely intervention. This is for the appropriate intervention and management which should be based on the causative pathology and not merely on the CTG pattern changes.

1. Slow Evolving Hypoxia

The stress of oxygen deprivation evolves over a time period like a few hours and hence fetus gets time for the compensation by activation of compensatory mechanism. The very first indicator is appearance of decelerations. The frequency, duration and amplitude depends upon the severity of the stress. The next is disappearance of accelerations in order to conserve the energy if the event is continuing. Subsequently fetal heart rate increases due to release of catecholamine as fetus tries to increase the heart rate and cardiac output for better perfusion of vital organs leading to fetal tachycardia (Figure 6).

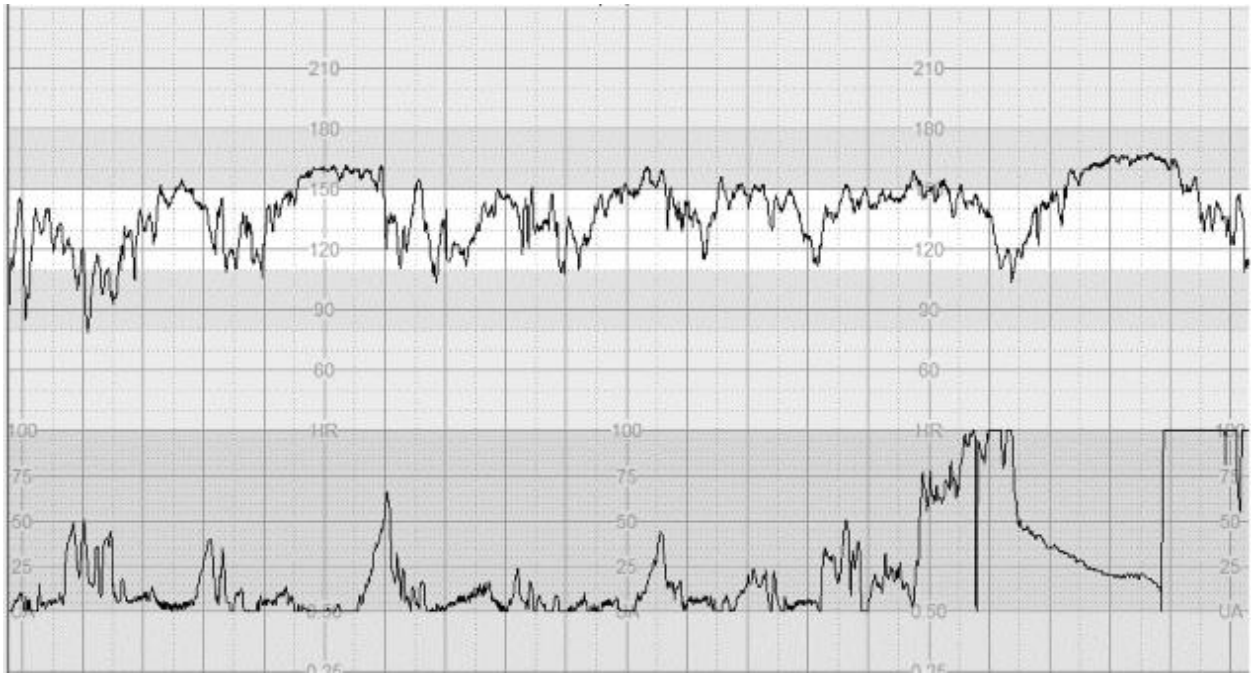


Figure.6 Repetitive decelerations which attributes to hypoxic stress, no acceleration, rise in baseline heart rate which attributes to catecholamine release.

The time duration when baby can sustain with the maximum heart rate depends upon the reserves. A study done by Fleischer et al. including patients with spontaneous onset of labour at term with reactive CTG at starting showed, that the development of acidosis depends upon the deceleration type. 50% of fetuses develop acidosis in the average time period of 115 minutes having recurrent late decelerations, 145 minutes for variable deceleration and 185 minutes with non-variable and flat CTG trace(55).

There is brain hypoxia due to insufficiency of oxygenation to carotid arteries. The loss of adequate brain perfusion leads to loss of variability. The undersupply of carotid arteries subsequently causes myocardial hypoxia followed by acidosis. After repeated trials to come back to baseline, terminal bradycardia develops preceding fetal death(Figure7)

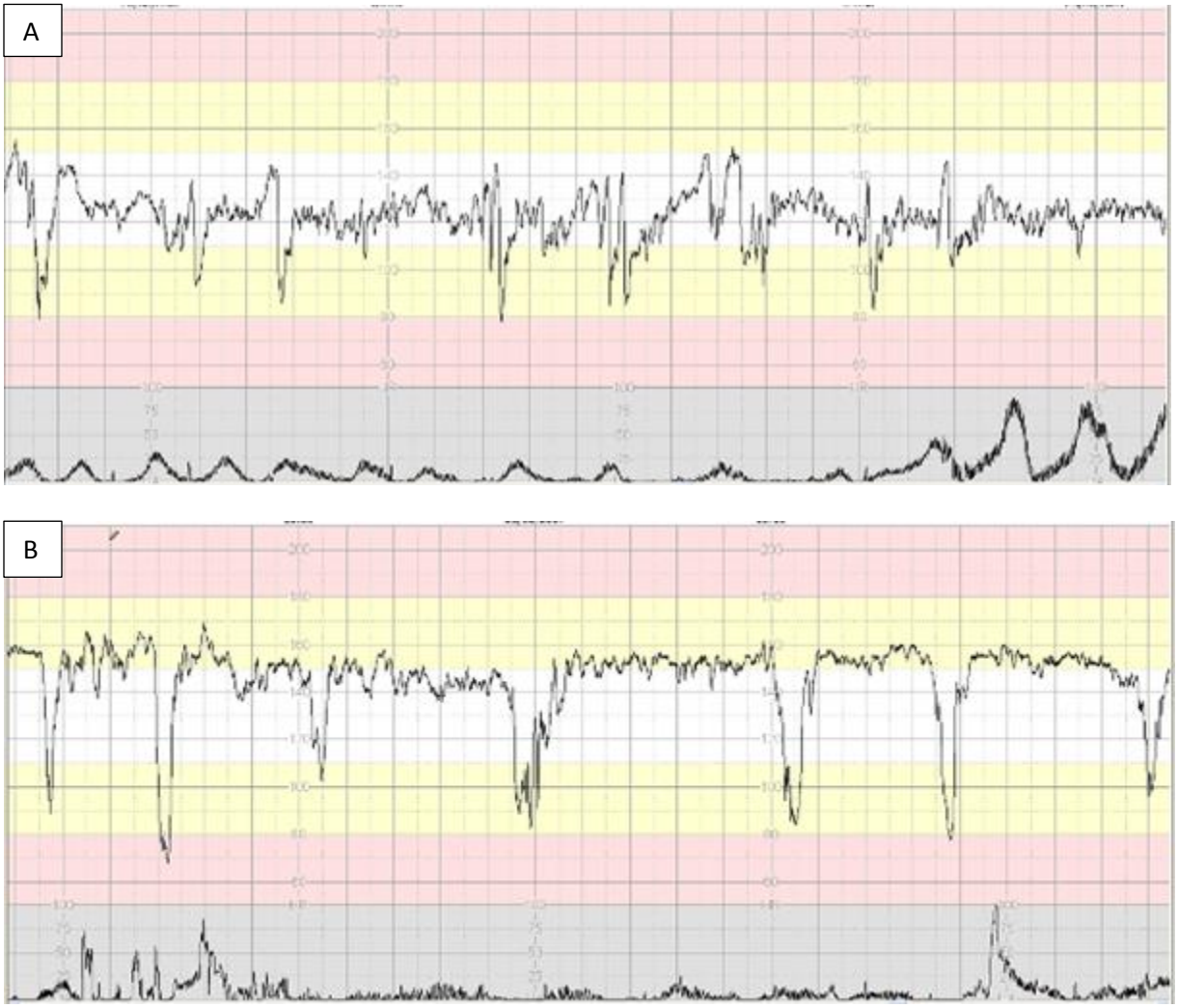
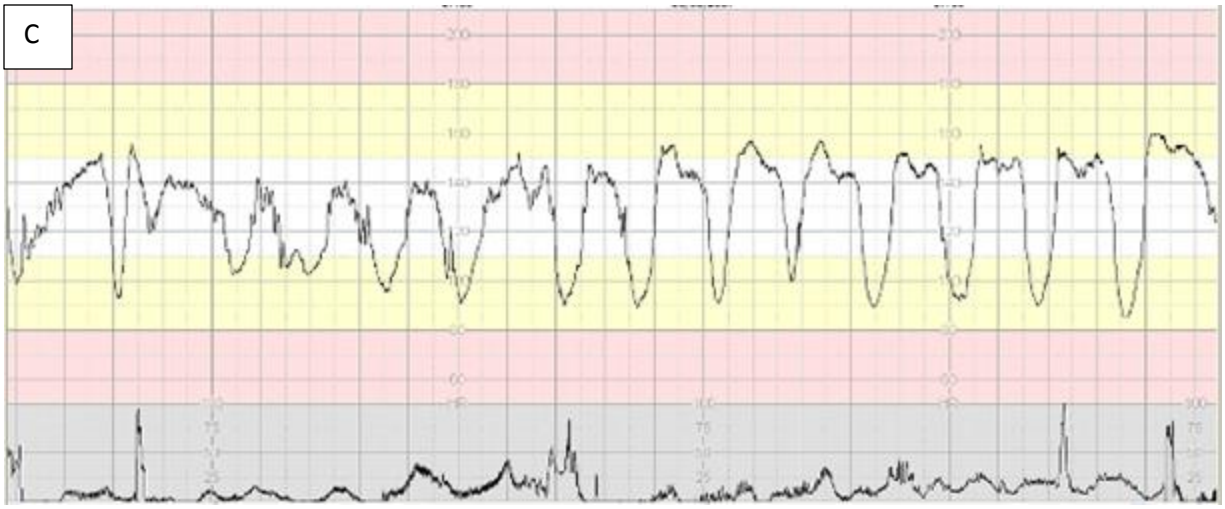


Figure7. (A-E) Shows slowly evolving hypoxia from the normal CTG, sequence of abnormality are appearance of decelerations followed by rise in baseline and then diminished variability. If the insult is not checked the terminal bradycardia ensues.

C



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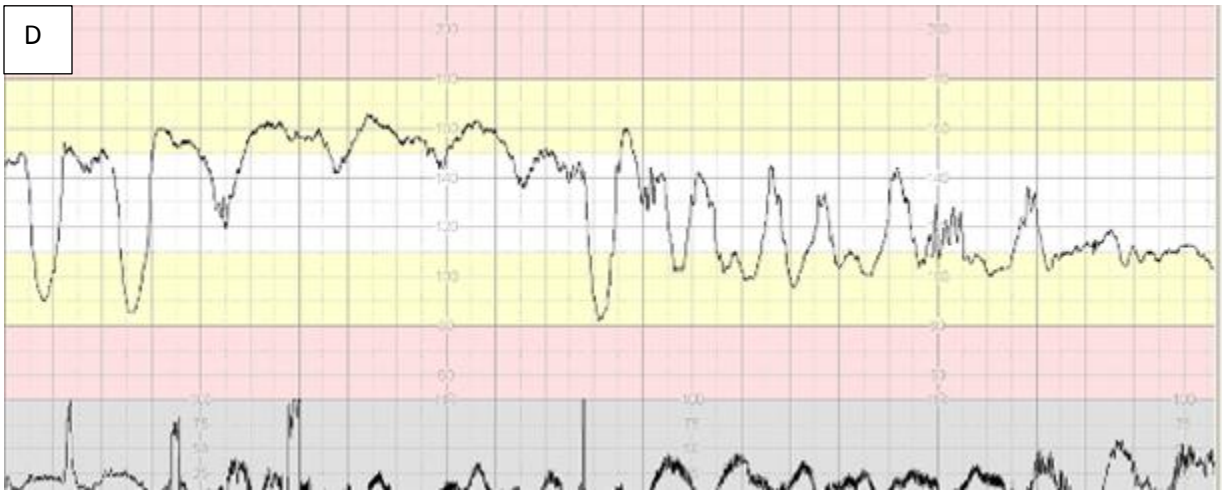

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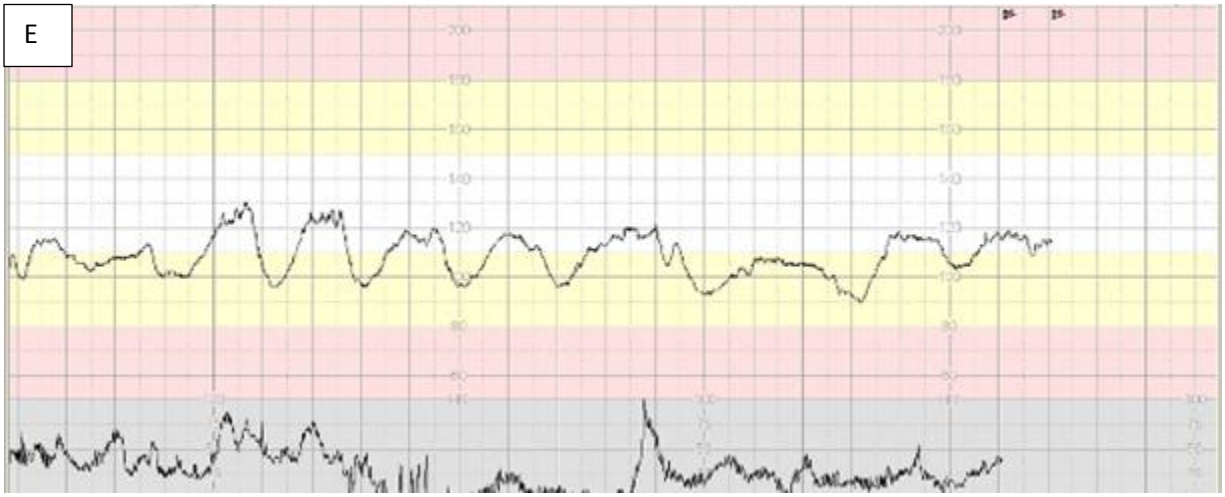


2. Acute Hypoxia

A single and prolonged deceleration where there is sudden fall in heart rate is the characteristic of acute hypoxia. It should be regarded as suspicious if last for <3 minutes and return to baseline with good variability. Deceleration lasting for >3 minutes is ominous and requires immediate intervention. The possibility of major mishaps cord prolapse, abruptio placentae or uterine rupture to be kept in mind where immediate delivery should be expedited. Other iatrogenic causes include, oxytocin infusion, supine position, epidural mediated hypotension. In these cases intrauterine resuscitation with hydration, stopping the oxytocin, changing the position, giving tocolytics such as terbutaline 0.25mg subcutaneously are beneficial(56). When there are no major mishaps as mentioned previously, 90% of prolonged decelerations are found to recover in 6 minutes and by 9minutes 95% should recover(57). Features which indicate reassuring status of fetus is presence of good variability in between the decelerations, drop in heart rate not < 60 bpm and absolutely normal CTG earlier to the occurrence of deceleration(58).

On the other hand the predictive features of poor outcomes are recurrent late decelerations, poor variability within 3 minutes of onset of deceleration and drop in heart rate >60bpm from the baseline(59)(Figure 8).

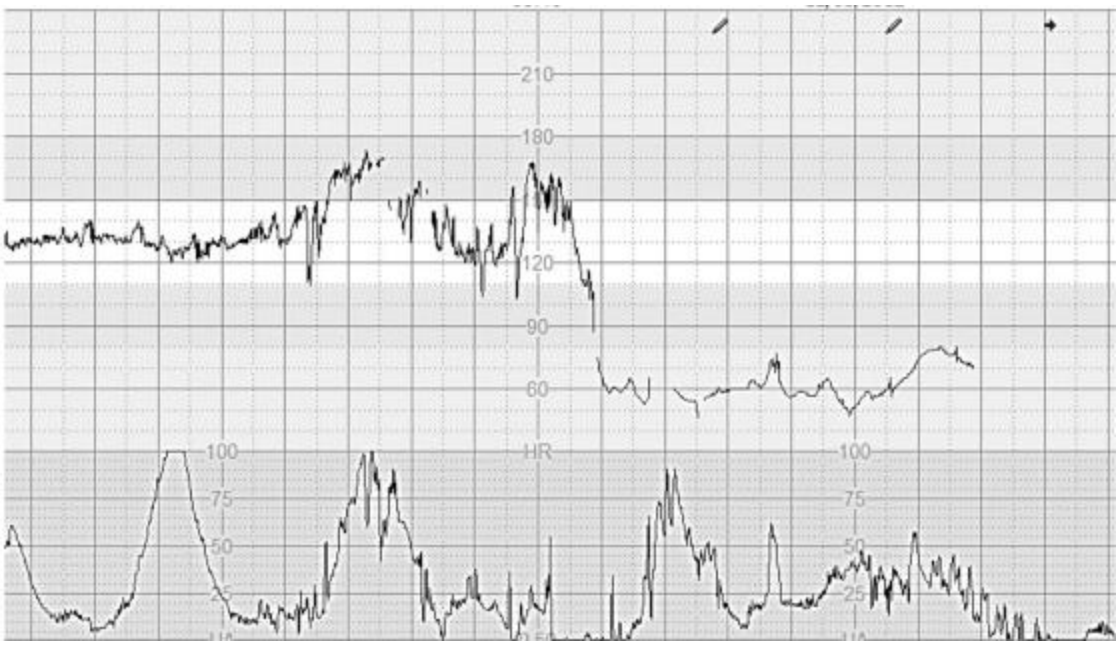


Figure8. Shows sudden drop of heart rate with very poor variability seen within 3 minutes of deceleration suggestive of acute hypoxia seen in cases like uterine rupture.

3. Subacute Hypoxia

There is complicated variable deceleration where the drop in heart rate is >60bpm and slow recovery over 90 minutes. There is widening and deepening of the ongoing deceleration. As the time spent by fetus baseline is short therefore the time available to get rid of the CO2 and acid is less. There is accumulation of CO2 leading to respiratory acidosis followed by metabolic acidosis. There is faster decline in pH than that in slow evolving hypoxia. In subacute hypoxia acidemia is of sufficient degree to employ reduction in vascular tone, hypotension and depressed myocardial activity leading to ischemic brain injury. Hence the identification of this CTG pattern is very

crucial(42,54)(Figure 9).

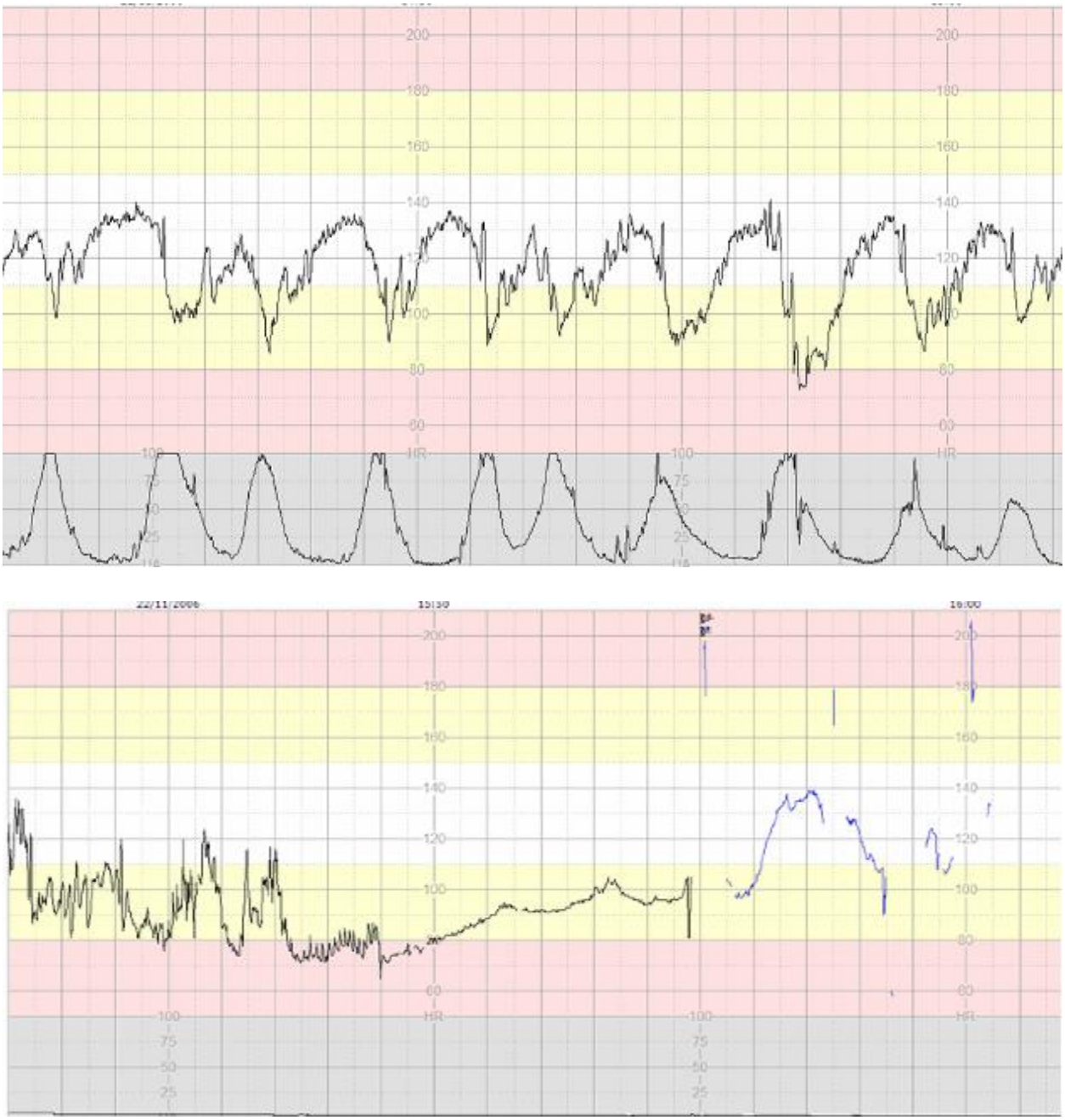


Figure9. CTG indicates that fetus spends less time at baseline than that at decelerations and ultimately leading to bradycardia.

4. Chronic Hypoxia

This is found in the condition where fetus has been going through long period of hypoxia starting from antenatal period itself. This is due to chronic utero - placental insufficiency. Fetus adapts to this environment by reducing the active movements and shunting the oxygenated blood to the vital organs from the non-vital organs. The inability to show compensatory response leads to evolving hypoxia and fetal acidemia. Animal study done by Pulgar et al. had shown that preexisting hypoxemia has deleterious effect on intrapartum fetal compensatory response(60). The classical CTG pattern with chronic hypoxia with neurological injury is characterized by following features; elevated baseline, poor variability and / or presence of shallow decelerations (Fig 10). The variability does not show any fetal cycling activity. This CTG pattern needs immediate delivery as further decrease in oxygenation due to intermittent cord compression and utero-placental circulation with the uterine contractions ultimately leading to myocardial failure as well as HIE(61).

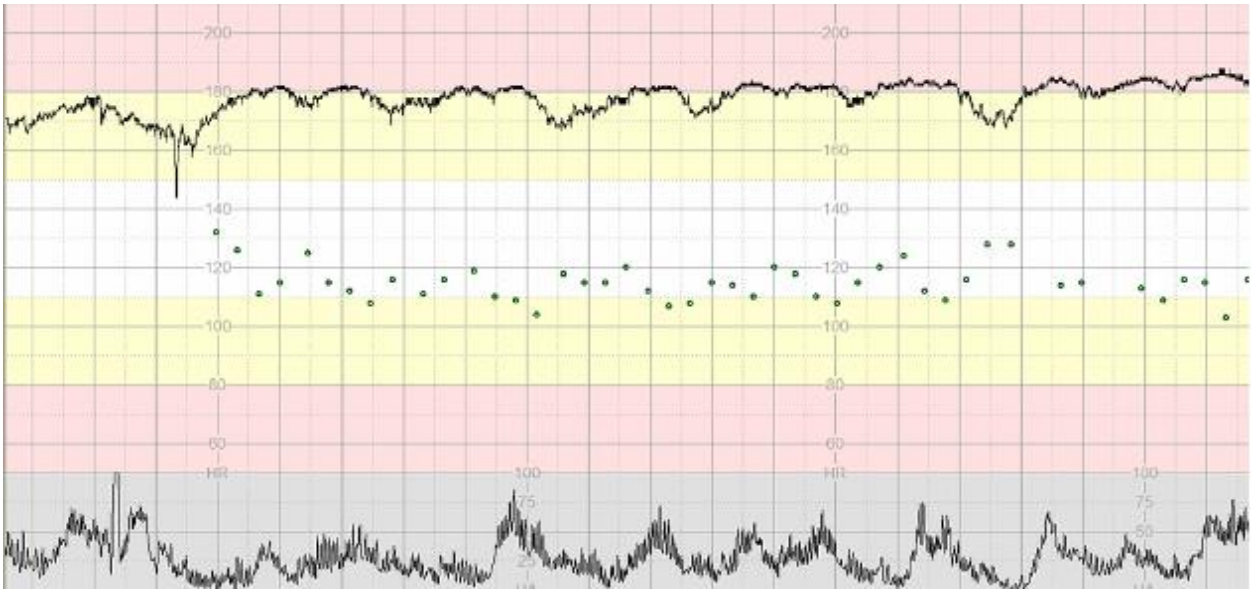


Figure 10.Shows evidence of chronic hypoxia with elevated baseline, reduced variability and shallow decelerations.

Severely fetal growth restriction develop acidemia very easily, display short period of bradycardia, quick return of heart rate to normal baseline after exposure to acute hypoxemia(62), tachycardia after recovery, all attribute to increase sympathetic tone.

Other CTG Patterns

Uterine hyperstimulation

Use of prostaglandins and oxytocin increases the frequency, amplitude and duration of uterine contractions which hamper the oxygenated blood flow into the intervillous space leading to fetal heart decelerations (Fig 11). Therefore continuous monitoring is important for patients on oxytocin infusion.

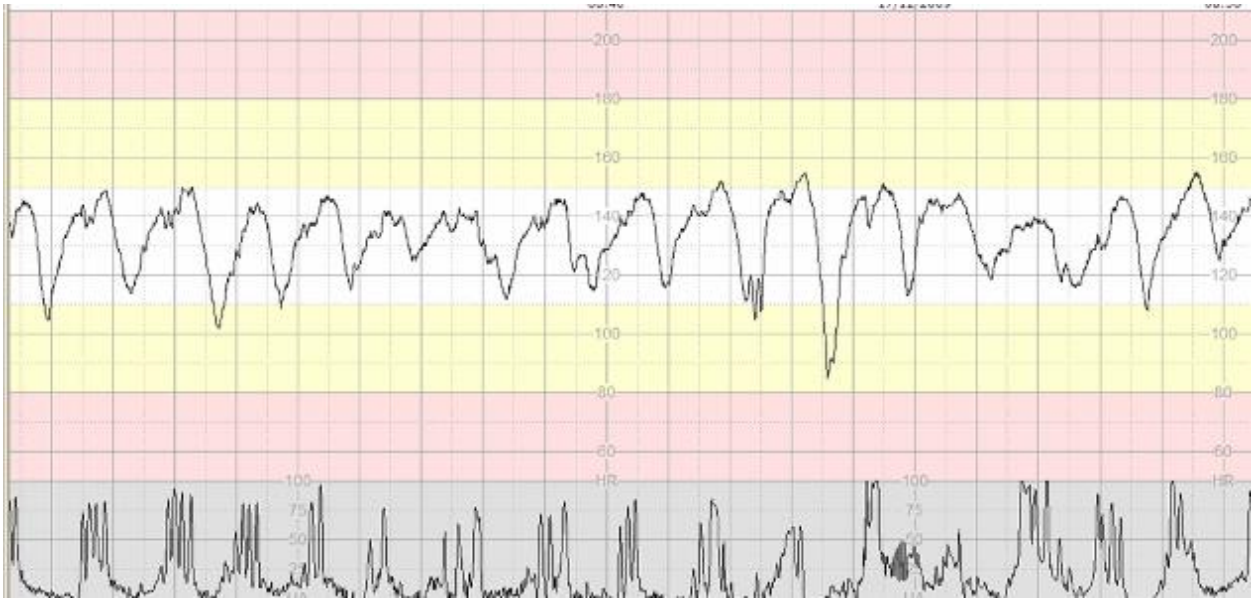


Figure11. With each uterine contractions appearance of deceleration of varying amplitude, also showing frequent contractions >6in 10 minutes where patient was on oxytocin.

Accidental Maternal Heart Rate Monitoring

During the second stage of the labour there may be collapse of fetal heart rate and CTG machine may catch and show the pulsation of maternal uterine vessels. These patterns can be misdiagnosed as reassuring fetal status. The broad accelerations on fetal monitoring coincides with the uterine contractions i.e., onset of the acceleration coincides with onset of contraction and offset of acceleration coincides with the offset of contraction(Figure 12)(42).

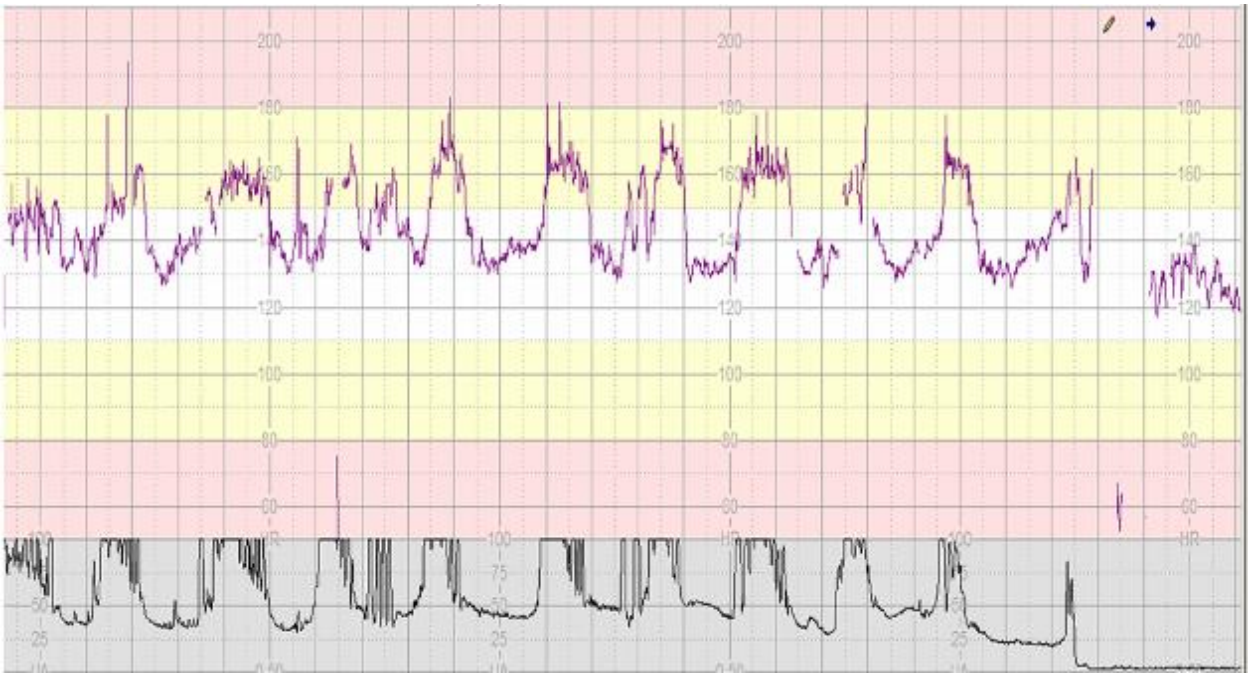


Figure12. Maternal heart rate coinciding with the onset and peak of uterine contractions seen with bearing down. The gigantic accelerations are characteristic of maternal heart trace.

Diagnostic Dilemma

Main problem with electronic monitoring is inter-observer and intra-observer bias. There are national guidelines for electronic fetal monitoring only for term fetuses and there is not sufficient recommendations for monitoring for preterm fetuses during labour (52). There are different classification systems. In an observational study where four observers studied 100 fetal heart patterns without any clinical information. The FHR patterns were classified by two- tier, three- tier and five-tier systems viz. reassuring and non-reassuring, NICHD 2008 and FIGO 2015, and CNGOF (French College of Gynecology

and Obstetrics) 2013 respectively. It was concluded that whichever classification is used the agreement of interpretation is moderate(63). Another observational study where the ACOG, FIGO and NICE guidelines were compared for interpretation, the reliability was markedly higher with FIGO and NICE than with ACOG, k=0.37and 95% CI 0.31- 0.43, k=0.33 and 95% CI 0.28-0.39, and k=0.15 and 95% CI 0.10-0.21respectively(64). A cross sectional study done by Bhatia et al. also showed to have suboptimal inter-observer agreement. FIGO system has favorable agreement and a moderate rate of intervention(65). According to Blackwell et al. inter-observer variability for category I and II traces were was moderate kappa 0.48 and 0.44 respectively. For category three trace the reliability was very poor in view of paucity of agreement regarding minimal and absent variability (kappa=0). However intra-observer agreement was almost up to the mark (kappa 0.74-1)(66). Despite having the expert algorithm for fetal heart rate interpretation which has potential to identify the traces before metabolic acidemia develops without increasing the operative intervention rate. Only 50% of the babies born with metabolic acidemia were identified earlier and delivered under ideal circumstances(67).

An observational study done to see the precision of electronic fetal monitoring in anticipating neonatal encephalopathy needing cooling therapy. It was found that the last hour of fetal heart tracing was poor predictor(68). It was said that specific features of fetal heart tracing is better predictor of neonatal outcome than the categorization of trace according to 3-tier system. Presence of following four features is the best predictor of fetal acidemia; baseline tachycardia, recurrent variable decelerations, recurrent late

decelerations, and recurrent prolonged decelerations(69).

Many experts recommend fetal scalp stimulation before embarking on the operative deliveries as they have acknowledged the limitation of electronic fetal monitoring for determining actual fetal status(70). The occurrence of acceleration due to scalp stimulation surely predicts the fetal pH to be 7.2 at this moment(71).

Recently a prospective observational study done by Ray et al. showed the specificity in detecting acidosis by CTG in case of indeterminate and abnormal categories is 56.91%. Whereas negative and positive predictive value are 92.72% and 29.33% respectively(72).

METHODS AND MATERIALS

Study setting

This study was a prospective observational study done in Christian Medical College and Hospital, a tertiary care center in Vellore district of Tamil Nadu, in Southern India. The study was approved by the Institutional Review Board (IRB) and ethics committee of our institution with IRB no. 10418 on December 5th 2016.

The study was conducted between December 2016 to September 2017 at Christian Medical College and Hospital, Vellore. Antenatal women admitted in the labour room with either spontaneous or induced labour, with an abnormal CTG tracing were recruited into the study after an informed consent.

Inclusion Criteria:

Women in labour, either spontaneous or induced, with singleton pregnancy, ≥37 weeks gestation, with fetus in cephalic presentation with

1. CTG pattern categorized as Category II according to NICHD classification
2. CTG pattern categorized as Category III according to NICHD classification

Women with any of the above CTG pattern during labour and who gave an informed consent were enrolled into the study

Exclusion Criteria:

1. Women in preterm labour i.e. gestation age <37 weeks

2. Women with abruptio placentae, cord prolapse, uterine scar dehiscence/rupture, vasa previa, anomalous fetus, and fetuses with congenital diaphragmatic hernia that need neonatal resuscitation

3. Women with growth restricted fetus with abnormal umbilical artery doppler

4. Women planned for elective Caesarean section

Data collection

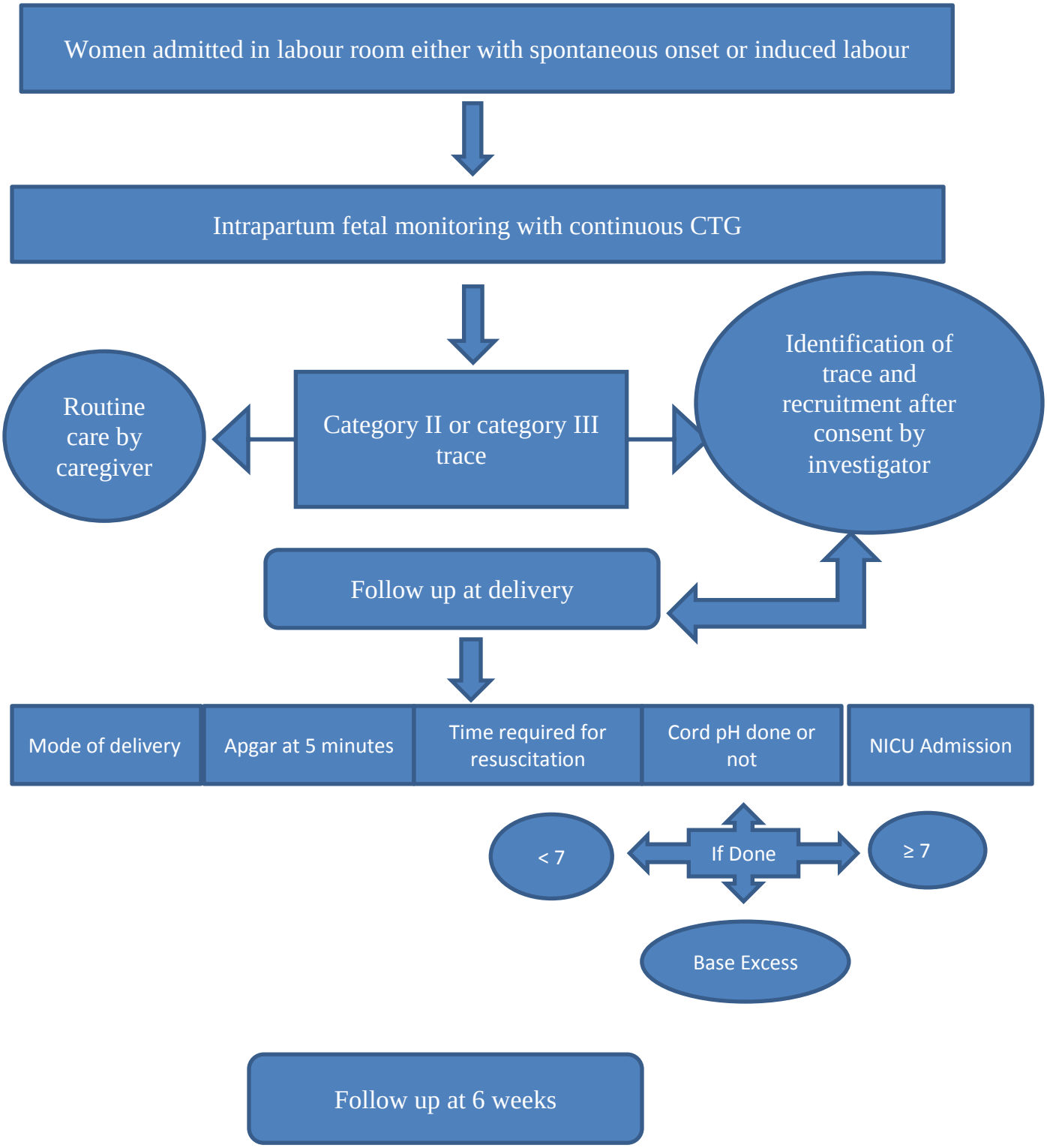
Women admitted in the labour room of our institution, who was in spontaneous or induced labour and who satisfied the inclusion criteria were explained about the study by the principal investigator, in the language best understood to them, which was either Tamil or English. Women, who gave an informed written consent, were enrolled into the study.

The demographic details of the patient, her obstetric score, any obstetric or medical risk factors and the onset of labour were noted down. If it was an induced labour, the indication for induction, method of induction and oxytocin augmentation if required were recorded. The colour of amniotic fluid at the time of rupture of membranes was recorded and if any amnioinfusion used was noted down. The presence of tachysystole or hyperstimulation requiring acute tocolysis with Inj. Terbutaline was also recorded in the proforma.

The routine labour management according to hospital protocol was continued and the decision regarding mode of delivery was taken by the senior registrars or consultants in labour room. Details of delivery i.e. mode of delivery, weight of the baby, Apgar score at 5 minutes, and resuscitation details like time required to resuscitate, if any, were recorded. If the woman had a caesarean delivery, the time of posting to delivery interval was noted down, to see if shorter intervals prevented acidemia in the newborn.

The CTG findings were noted down with regard to the baseline heart rate, presence or absence of accelerations, variability, type and severity of decelerations and duration of abnormal CTG pattern prior to delivery. Definitions given by FIGO were used, for normal baseline heart rate, normal, moderate or poor variability, accelerations and decelerations. The CTG pattern was then categorized into Category II or III according to NICHD classification. Newborns, who had the above categorized abnormal fetal heart rate pattern, and who required a cord blood gas due to low Apgar scores or because they were depressed at birth were followed up, if they were admitted in the Neonatal intensive care unit. The details of the cord blood gas were also noted down. The number of days the baby stayed in neonatal intensive care unit and the course in hospital was noted. Once the babies were discharged we have called them for a review check-up 6 weeks later, which is yet to be completed.

The summary of follow up plan for the study cohort



Sample Size calculation

The primary objective of the study is to study the perinatal outcome and that will be assessed by abnormal CTG patterns includes category II and III.

For the sample size calculation, the statistical input of abnormal CTG patterns (category II and III) are taken from the following reference article "Cardiotocography patterns and risk of intrapartum fetal acidemia"(19).

For each abnormal CTG patterns, the sample size is calculated. Finally the maximum number will be considered as final sample size. The sample size is calculated using n Master software version 2.0.

Sample size was calculated as below

$$n = \frac{Z^{2}_{1-\alpha/2}\, p(1-p)}{d^{2}}$$

Where,

p : Expected proportion

d : Absolute precision

1- α/2 : Desired Confidence level

N=189

With the expected proportion of 0.144, precision as 5% and 95% confidence interval, this study requires totally around 190 patients to study the perinatal outcome.

Statistical Methods

For continuous data such as age, the descriptive statistics n, Mean, Standard Deviation, Median, Inter Quartile Range, Minimum and Maximum will be presented.

For categorical data, the frequencies and percentage will be presented. Based on the normality of data, the parametric t test or non-parametric Mann Whitney test will be applied to the data if it is required. The Chi-square or Fisher's exact test will be applied to the data. P-values will be reported as specified by the statistical software used, at least up to four decimal places.

P-values less than 0.0001 will be reported as provided by statistical software (e.g. '<0.0001').All tests will be two-sided at α=0.05 level of significance. Other statistical test will be carried out if it is deemed. All statistical analysis will be done using SPSS software version 17.0 or later.

Predictors: Predictors, potential confounders and effect modifiers

a. Severe Feta Growth Restriction (FGR)

b. Meconium stained amniotic fluid

c. Maternal tachycardia or pyrexia

d. Presence of chorioamnionitis

e. Prolonged second stage

f. Pregnancy following subfertility or assisted reproductive techniques

g. Difficult instrumental delivery

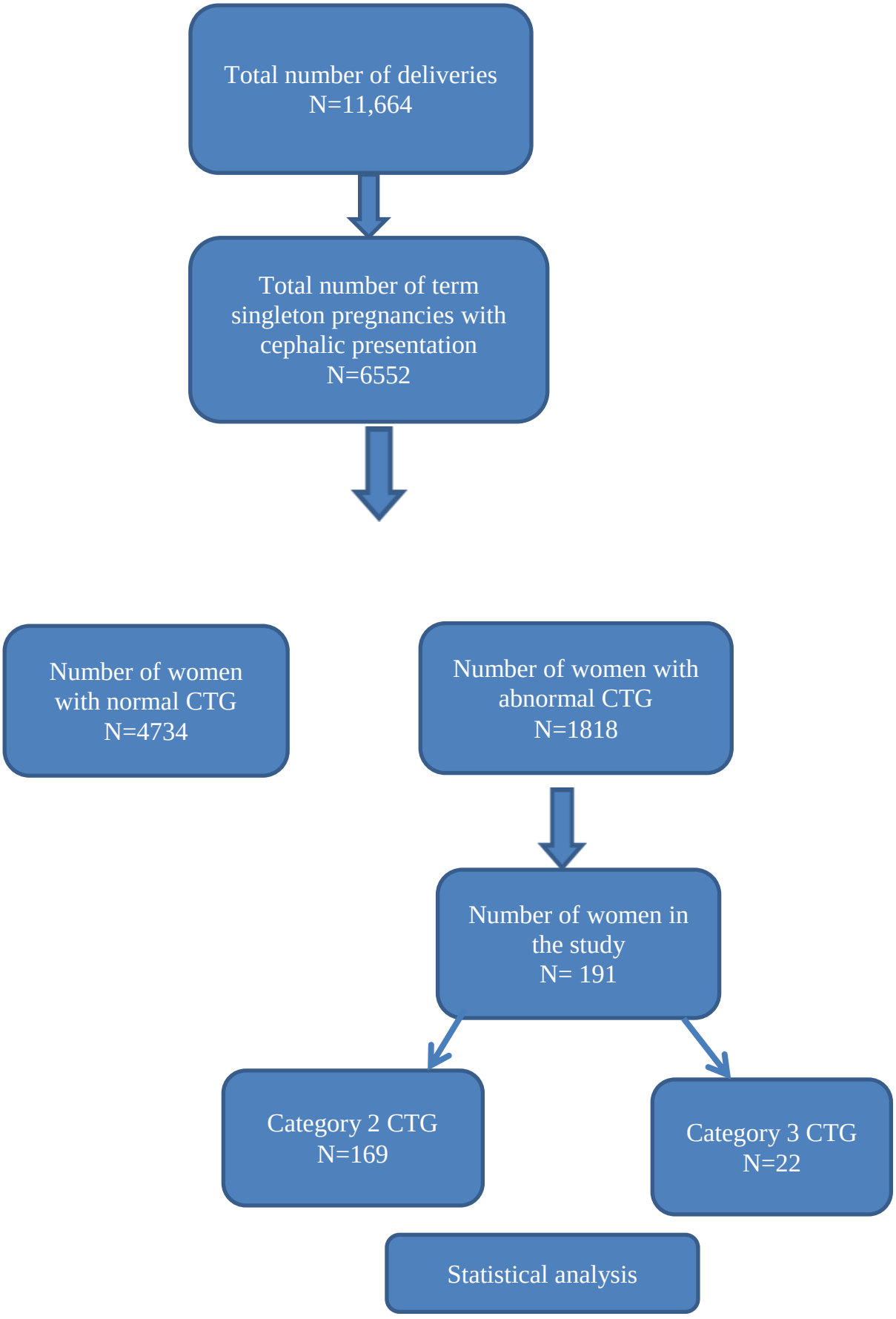
i. Decision to intervene to delivery time

j. Previous history of adverse perinatal outcome

Bias

Interpretation of trace could vary between attending obstetricians, but the chance of Inter-observer variation was less. Though principle investigator has reviewed and Interpreted the traces to minimize the bias, chances of intra-observer bias is always there. The decision for posting for caesarean delivery also varies among the consultants covering labour room hence the duration of non-reassuring fetal status varies which in turn affects the outcome.

RESULT


Total number of deliveries
N=11,664
Total number of term singleton pregnancies with cephalic presentation
N=6552
Number of women with normal CTG
N=4734
Number of women with abnormal CTG
N=1818
Number of women in the study
N= 191
Category 2 CTG
N=169
Category 3 CTG
N=22
Statistical analysis

this study we recruited191 women with an abnormal CTG during labour, out of which 169(88.5%) women had a category II CTG according to NICHD classification and 22 (11.5%) women had a category III CTG (Figure 1)

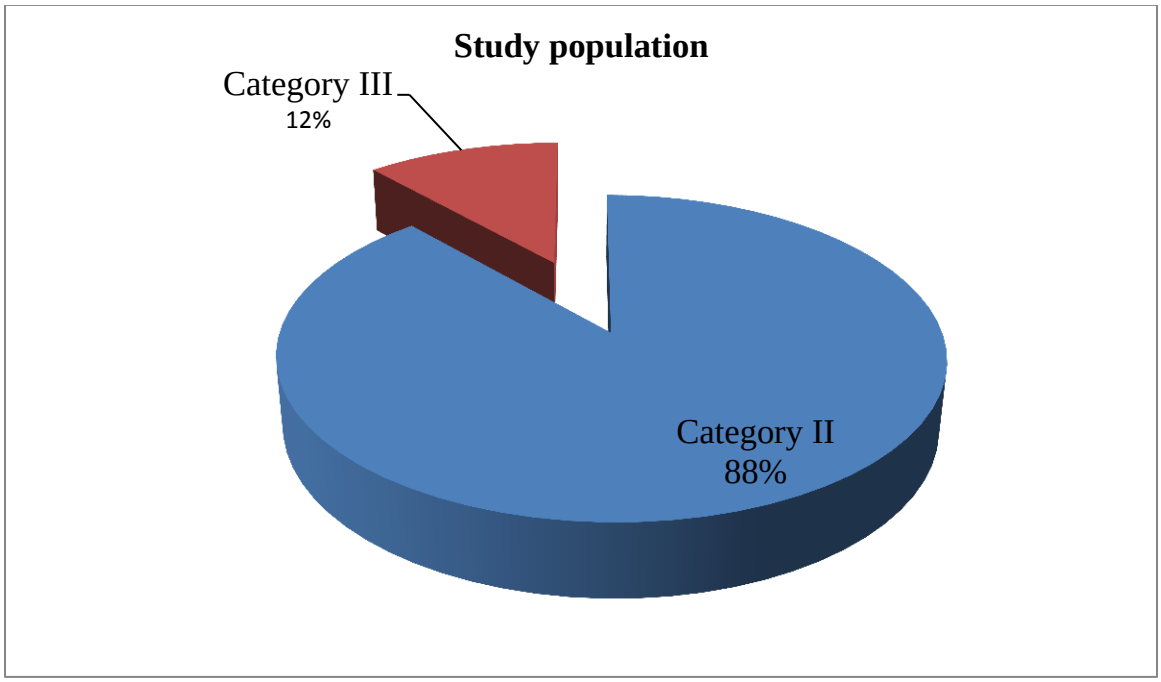


Figure1: shows the total number of women in this study and their CTG categorization

Table 1: Characteristics of the study population

Characteristics	
Maternal age (years)	26.09[a] (17 – 39)[b]
Gestational age (weeks + days)	39+0.06[a] (37 - 41+1)[b]
Nulliparous n (%)	162 (84.8)
Labour Onset n (%)	
Spontaneous	72 (37.7%)
Induced	119 (62.3%)
MSAF n (%)	54 (28.3)
Oxytocin Augmentation n (%)	161 (84.3)
Delivery mode n (%)	
Caesarean section	71(37.2)
Operative vaginal	116(60.7)
Spontaneous vaginal	4(2.1)
Birth weight (g)	2924[a] (1860-3840)[b]

a =mean, b =range

A univariate analysis was done for some of the characteristics of the women in our study (Table 1). The mean age of the women in this study was 26 years which ranged from 17 years to 39 years. The women had term pregnancies with gestational age ranging from 37 weeks to 41 weeks 1day with a mean gestational age of 39 weeks. Most of the women in our study were primigravidas (84.8%).

Among the 191 women in this study there were 119(62.3%) women whose labour was induced, 72 (37.7%) of them had a spontaneous onset of labour and 84.3% (161/191) of them required labour augmentation with oxytocin.

There were 54(28.3%) women who had meconium stained amniotic fluid at the time of rupture of membranes.

Of these 191 women, 120 women delivered vaginally and 71 (37.2%) women delivered by a caesarean section. Of the 120 women who delivered vaginally, 116(60.7%) women needed an instrumental delivery.

The mean birth weight of the babies born to these 191 women was 2924g.

Table 2: Obstetric and medical risk factors in the study group

Risk Factors	Total number (191) (100%)
Gestational Diabetes Mellitus	32(16.8)
Pre-gestational diabetes	2(1)
Gestational Hypertension	9(4.7)
Chronic HTN	2(1)
Mild Pre-eclampsia	2(1)
Severe Pre-eclampsia	2(1)
Advanced Maternal Age (≥35 years)	8(4.2)
Hypothyroidism	15(7.9)
Anemia	5(2.6)
Short Stature (≤145 cm)	2(1)
Other Maternal Risk Factors *	8(4.2)

*Includes Bronchial asthma, seizure disorders, autoimmune diseases, chronic hepatitis, infertility, Rh negative pregnancy etc.

Table 2 shows the various obstetric and medical risk factors among the women in this study. The most common risk factor was gestational diabetes mellitus (GDM), which was present in 16.8% of the women who participated in the study. Hypothyroidism was seen in 7.9% of the women and was the second most commonly seen medical disorder in this study group. Other medical conditions were gestational hypertension (4.7%) and anemia

(2.6%). There were 8(4.2%) women in this study who were aged more than 35 years and hence were at high risk for medical disorders as well as obstetric complications.

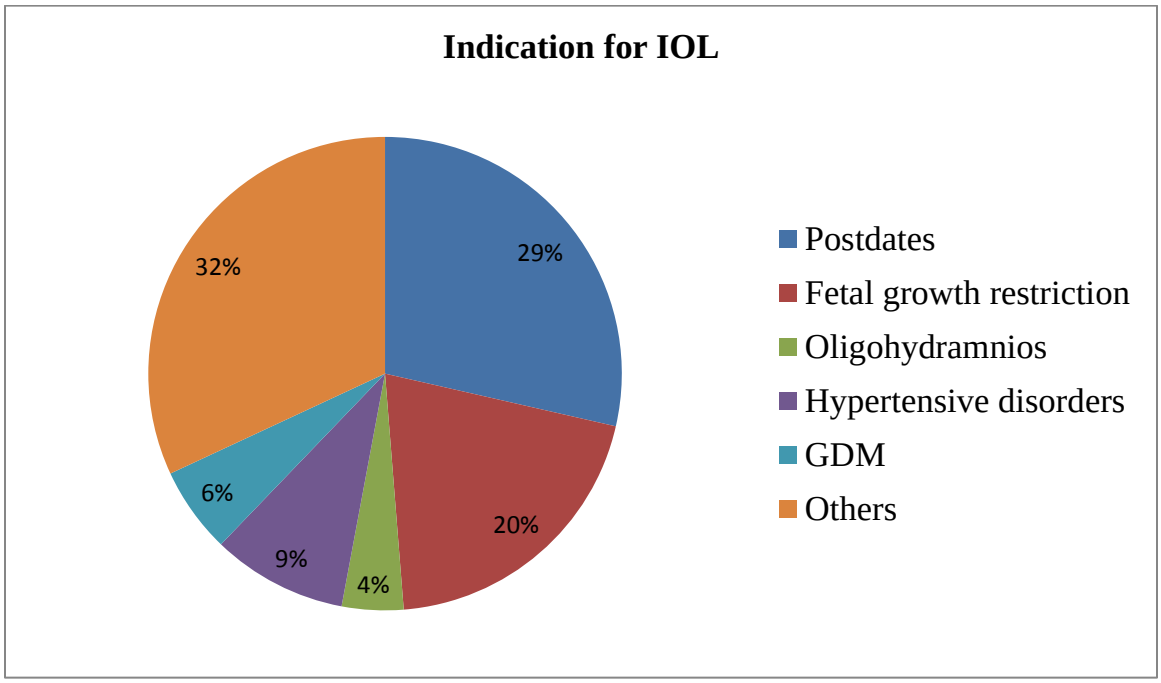


Figure 2: shows the indication for induction of labour (IOL)

There were a total of 119 (62.3%) women who had an induced labour. The various indications for induction of labour are shown in Figure 2. Twenty nine percent (34/119) of women were induced for past dates, was the most common indication for induction among our study population. There were 24 women induced due to growth restricted fetuses (FGR) which was the second most common indication (20%). Other indications were gestational diabetes mellitus(GDM) (6%), hypertensive disorders (9%),

oligohydramnios (4%) and other less common indications like decreased fetal movements at term, IVF pregnancy, advanced maternal age and obesity which accounted for a total of 32% of the indications for induction of labour (38/119).

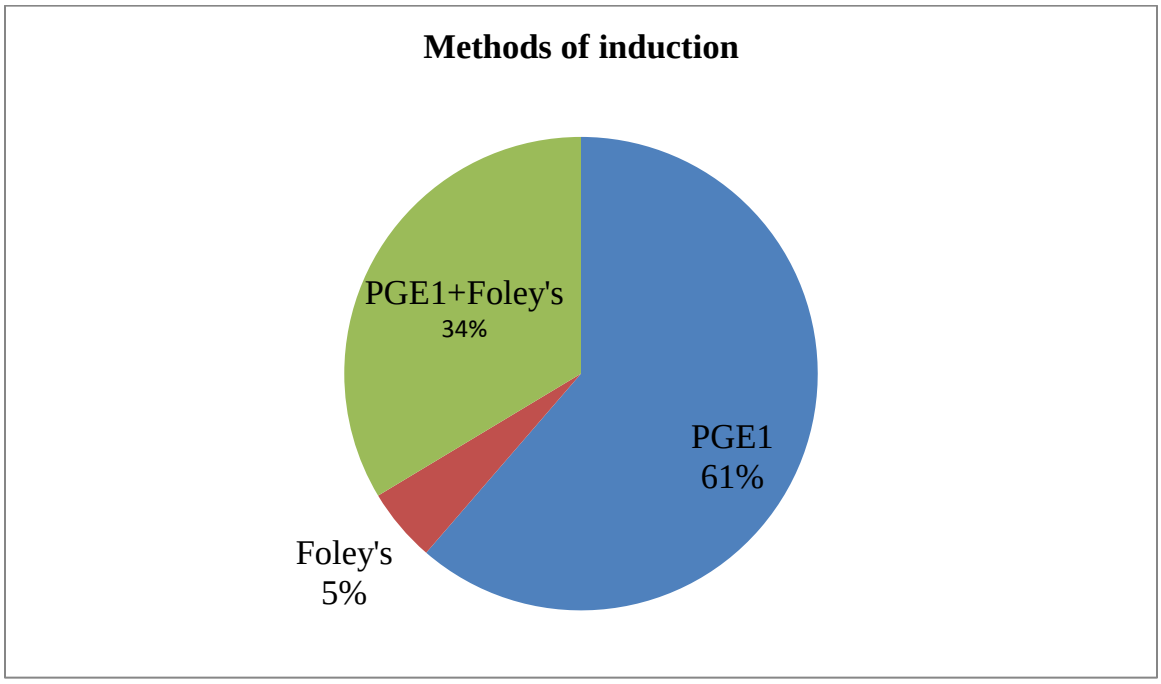


Figure 3: Methods of induction of labour

The methods of induction of labour were either using vaginal Misoprostol (PGE1) at a dose of 25mcg every 6 hours of 2-3 doses, mechanical dilatation of the cervix using Foley's catheter and inflating the bulb with 30ml of distilled water or with both simultaneous. As shown in figure 3, most of the women were induced with vaginal Misoprostol followed by the combined method. There were 5% of women who had a

mechanical dilatation of the cervix with Foley's catheter alone and this was mostly done for women with a growth restricted fetus or those with severe oligohydramnios.

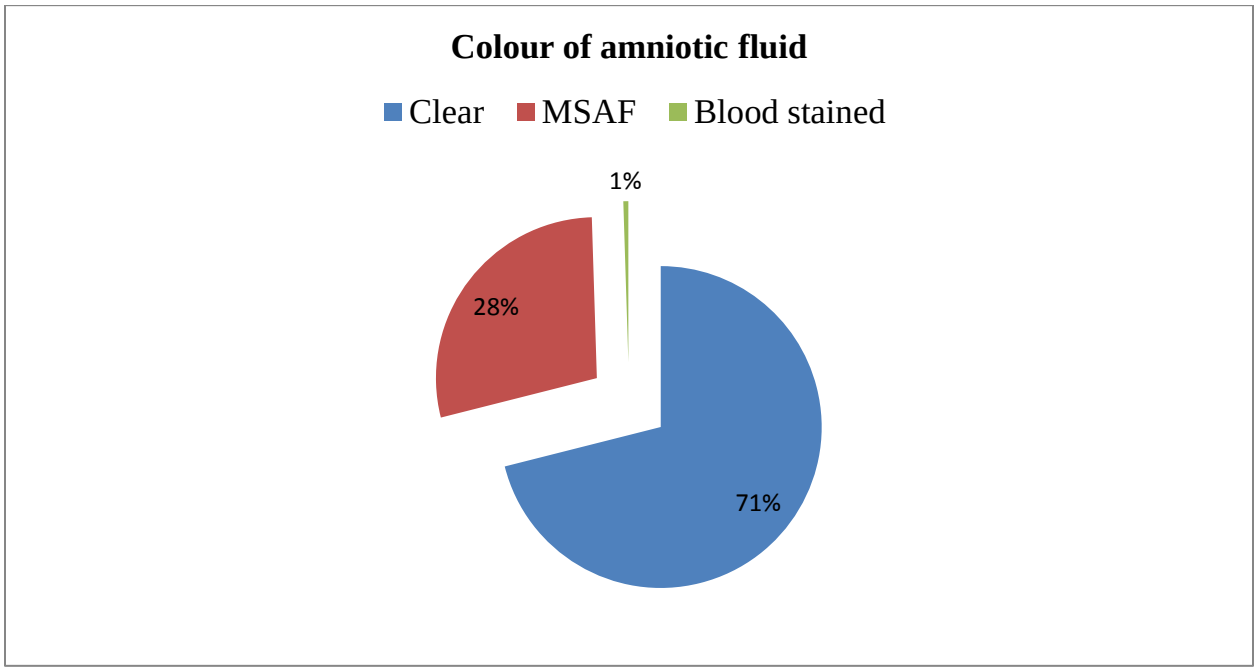


Figure 4: shows the colour of liquor at the time of rupture of membranes

There were almost 71% women who had clear liquor intrapartum, 28.3% had meconium stained amniotic fluid and one woman who had blood stained liquor during amniotomy (Figure 4).

Among the women in this study 169 (88.5%) women had category II CTG and 22 (11.5%) of them had a category III CTG (Figure 1). The individual components of the CTG i.e. baseline heart rate (BHR), fetal heart rate variability, accelerations and decelerations and their various types were recorded for each CTG trace. These individual components were then correlated to the degree of neonatal depression if present. It was seen that variable decelerations were more often seen during labour as depicted in

figure 5. Among variable decelerations 71.97% were non-severe and 28.03% were severe.

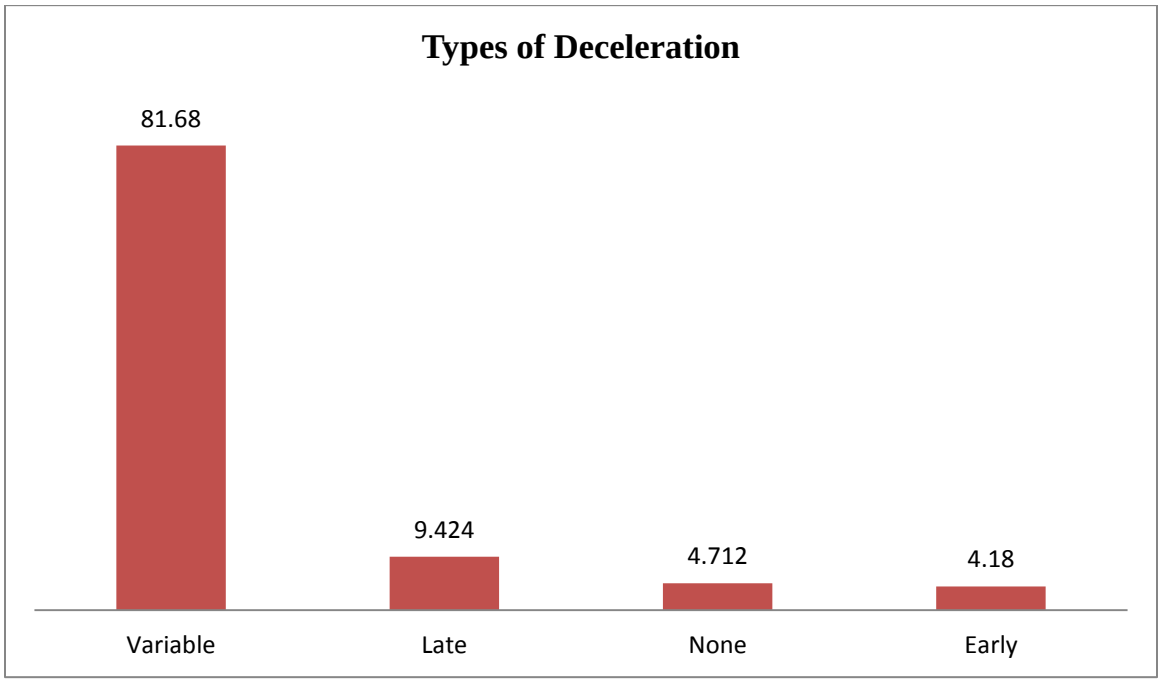


Figure 5: Various types of decelerations encountered during labour

Table 3: NRFS categories and Apgar at 5 minutes

Apgar at 5 minutes	NRFS Category		Total	
	II	III		
6	1(0.6%)	0	1	
7	1(0.6%)	0	1	P-value 1
8	3(1.8%)	3(13.6%)	6	
9	17(10.1%)	9(40.9%)	26	
10	147(87%)	10(45.5%)	157	
Total	169	22	191	

Of the total babies born to the women in this study, 82.2% (157/191) had Apgar 10 at 5 minutes. There were 2 (1%) women whose babies had an Apgar ≤ 7 and they had a category II CTG trace before delivery. There was no statistically significant correlation between 5 minute Apgar scores and the abnormal CTG tracing before delivery (p value 1).

One of the methods to evaluate the neonate for adverse perinatal outcome is checking for the cord blood gases. In this study there were 11(6.5%) women who had a category II CTG trace and 11 (50%) with category III CTG trace before delivery, whose babies needed a cord blood gas for further evaluation and management of birth asphyxia, as these babies were depressed at birth and needed resuscitation by various methods. As cord pH<7 depicts severe asphyxia that leads on to neonatal morbidity and mortality, we

looked at neonates who had a cord pH <7 and evaluated if it correlated with the category of the abnormal CTG.

Table 4: Cord pH vs. CTG category

Cord pH	NRFS Category		Total	
	II	III		
<7	2(18.2%)	1(9%)	3	P-value 1
7	9(81.8%)	10(91%)	19	
Total	11(100%)	11(100%)	22	

Table 4 shows the cord pH done in 22 babies. From this table we can see that there were 3 babies whose cord pH was <7. Two of these babies had shown a fetal heart rate pattern that of category II trace and 1 baby that of category III trace. In this study there was no significant increase in the number of babies with a low cord blood pH even with a category III CTG trace (p value 1)

Table 5: NRFS Category vs. requirement of NICU admission

NICU Admission	NRFS Category		Total	P-value
	II	III		
Yes	7(4.1%)	9(40.9%)	16(8.4%)	<0.0001
No	162(95.9%)	13(59.1%)	175(91.6%)	
Total	169	22	191	

There were a total of 16 babies who required admission into the neonatal intensive care unit (NICU) as they were depressed at birth. Among the fetuses who presented with a category II CTG trace, 7 babies (4.1%) needed admission and 9(40.9%) babies who had presented with a category III fetal tracing required admission to NICU. There was a statistically significant increase in admission to NICU with a category III CTG tracing (p value <0.0001) (Table5).

Table 6: Correlation between neonatal problems encountered during the hospital stay of the babies who were depressed at birth and the CTG category

Neonatal Problems	NRFS Category		Total	
	II	III		
HIE Stages	1(16.7%)	2(25%)	3(21.4%)	P-value
Metabolic acidosis	2(33.3%)	4(50%)	6(42.9%)	0.8
RDS	3(50%)	2(25%)	5(35.7%)	
Total	6(100%)	8(100%)	14(100%)	

Of the 16 babies who were admitted in the NICU, 14 babies developed problems which required further evaluation, monitoring and specialized care. Two of the babies were kept under observation and discharged well without any sequelae. Three (21.4%) babies developed hypoxic ischemic encephalopathy (HIE) of varying degrees, 6 (42.9%) babies had a metabolic acidosis which required correction and 5 (35.7%) babies developed respiratory distress syndrome (RDS). In this study we found that fetuses who presented a category III heart tracing during labour were more likely to develop HIE and metabolic acidosis though it was not statistically significant from babies who had had a category II trace (p value 0.8).

Now we looked into the various components of the CTG i.e. baseline heart rate, fetal heart rate variability and the types of decelerations and evaluated if there was a correlation between the individual components and adverse perinatal outcome.

Table 7: Correlation between type of variability in the CTG and requirement of cord blood gas for further evaluation

Cord pH done	Variability			Total	
	Good	Moderate	Poor		
Yes	2(10.5%)	8(42.1%)	9(47.4%)	19(100%)	P-value 0.013
No	52(30.2%)	89(51.7%)	31(18%)	172(100%)	
Total	54(28.3%)	97(50.8%)	40(20%)	191	

Of 191 CTG traces 40(20.9%) showed poor variability, 97(50.8%) showed moderate variability and 54(28.3%) traces showed good variability. Of 19 babies who required cord pH for further evaluation of birth asphyxia , there were 9(47.4%) babies whose CTG had shown a poor fetal heart rate variability, 8(42.1%) who had moderate variability in the CTG and 2(10.5%) whose fetal heart rate variability recorded in the CTG was good. Thus we found that poor variability is strongly associated with babies being depressed at birth thus requiring a cord blood gas evaluation for further evaluation and treatment (p-value 0.013) (Table 7).

Table 8: Correlation between types of variability in the CTG with NICU admission

NICU Admission	Variability			Total	
	Good	Moderate	Poor		
Yes	0	8(8.2%)	8(20%)	16(8.3%)	P-value
No	54(100%)	89(91.8%)	32(80%)	175(91.7%)	0.006
Total	54(100%)	97(100%)	40(100%)	191	

In this study there were 16(8.3%) neonates who were admitted to NICU as they were depressed at birth. Among the ones who had a poor variability trace in the CTG, 8 neonates (20%) required NICU admission, 8 (8.2%) babies among the ones who had a moderate variability CTG trace needed NICU admission and all the babies who had a good variability CTG trace were by their mother's side after birth. Here again it is seen that poor variability was significantly associated with adverse perinatal outcome requiring NICU admission (p-value 0.006) (Table 8) but it was not significantly more than the ones who had a moderate variability (p value 0.053).

In the 191 women's CTG that we studied, the baseline heart rate was normal in most of the patients and hence we did not look into the correlation between the baseline heart rate and adverse perinatal outcome.

We looked into the decelerations and the types of decelerations that were seen in the CTG traces that we studied and correlated them to adverse perinatal outcome. There were early, late and variable decelerations among the various CTG traces that we studied.

The most common deceleration encountered during labour among the study population was variable deceleration (81.68%) (Figure5).

There were 182 among the 191 CTG traces that we studied with the presence of decelerations. Out of these, there were 2 (1%) babies who had Apgar ≤7 at 5 minutes and the corresponding CTG done during labour showed variable decelerations. Thus there were 99% of babies who had a normal Apgar at 5 minute even if the CTG trace during labour was abnormal with the presence of decelerations.

The variable decelerations were of the severe type in both these babies' CTG. There was no statistically significant correlation between severe variable decelerations and low Apgar scores at 5 minute in this study (p-value 0.05).

Table 10: Correlation between variable deceleration and the need for cord blood gas evaluation

Cord pH done	Variable		Others	Total	
	Severe	Non-severe			
Yes	9(20.5%)	5(4.4%)	5(14.7%)	19	P-value
No	35(79.5%)	108(95.6%)	29(85.3%)	172	0.005
Total	44(100%)	113(100%)	34(100%)	191	

We then evaluated the correlation between deceleration and the need for cord blood gas for babies who were depressed at birth. There were 44 CTG traces which had severe variable deceleration and 113 with non-severe variable decelerations. The remaining 34 traces had other features that described the CTG as abnormal. Among the 44 neonates who had severe variable deceleration in their respective CTG trace, 9(20.5%) of them required a cord blood gas for further evaluation of birth asphyxia and 5(4.4%) from those who had a non-severe variable deceleration in the CTG trace needed a cord blood gas. The neonates who had a CTG trace with severe variable deceleration thus needed a cord blood gas for further evaluation and this association was statistically significant (P-value 0.005) (Table 10). Hence we see that severe variable decelerations are more often associated with neonates who depressed at birth requiring a cord blood gas for further evaluation.

At the same time we also found that NICU admissions for neonates who had a CTG trace with severe variable deceleration were higher than in other abnormal traces (18.2% vs. 5.3%) and it was statistically significant (p value 0.047) (Table 13)

Table 11: Variable deceleration vs. NICU Admission

NICU Admission	Variable		Others	Total	
	Severe	Non-severe			
Yes	8(18.2%)	6(5.3%)	2(5.9%)	16	P-value 0.047
No	36(81.8%)	107(94.7%)	32(94.1%)	175	
Total	44(100%)	113(100%)	34(100%)	191	

Table12.Summary of associations with NRFS category

Variables	NRFS Categories		P-value
	II N (percentage %)	III N (percentage %)	
5 minute Apgar <7	2(1%)	0	1
Cord pH <7	2(18.2%)	1(9%)	1
NICU Admission	7(4.1%)	9(40.9%)	**<0.001**
Neonatal Problems	6(42.9%)	8(57.1%)	0.8

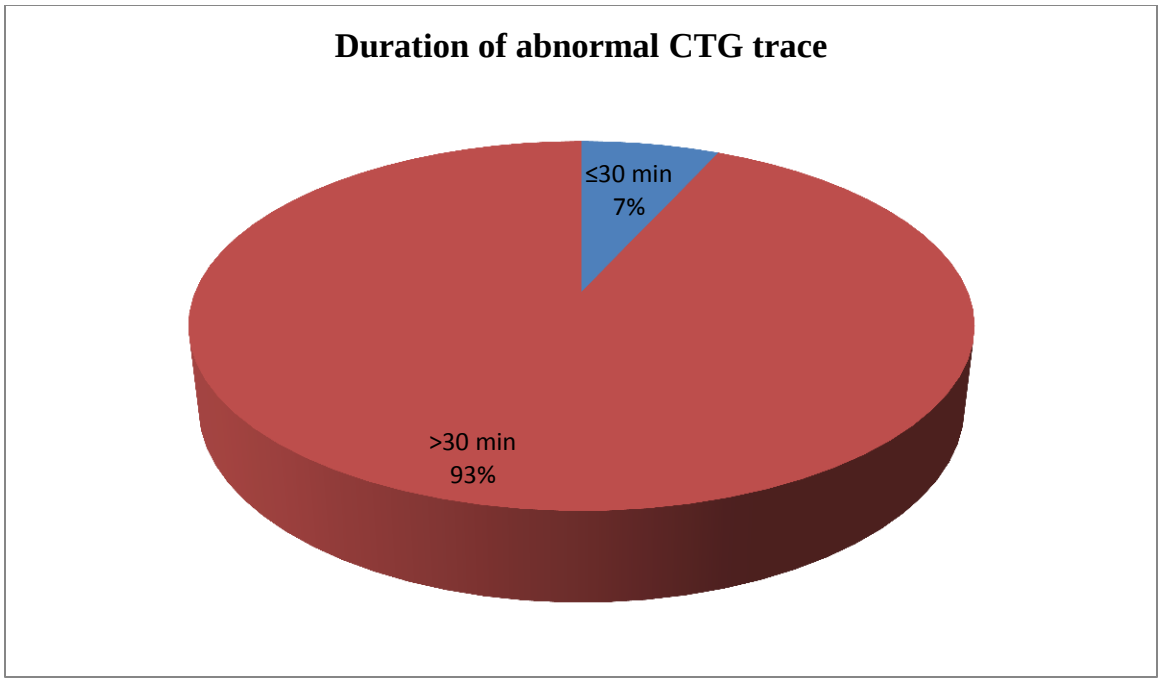


Figure 6: shows the duration of abnormal CTG trace

Apart from the category of the CTG trace and its various components correlating with the severity of adverse perinatal outcome, we also evaluated if the duration of the abnormal CTG had a bearing on the outcome, i.e. adverse perinatal events. In this study there were 13 CTG traces which were abnormal for a time period of <30 minutes and the remaining 178 traces were abnormal for more than 30 minutes (Figure 6).

Table 13: Correlation between duration of abnormal CTG trace and Apgar at 5 minutes

Duration of NR trace	Apgar 5 Minutes					Total
	6	7	8	9	10	
≤ 30 min	0	0	0	1	12	13
> 30 min	1	1	6	25	145	178
Total	1	1	6	26	157	191

Table 14: Duration of NRFS and NICU admission for Neonatal depression

Duration of NR trace	NICU Admission for Neonatal Depression		Total
	Yes	No	
≤ 30 min	0(0%)	13(7.4%)	13(6.8%)
> 30 min	16(100%)	162(92.6%)	178(93.2%)
Total	16	175	191

It was seen in this study that the duration of abnormal CTG trace was inversely proportional to the 5 minute Apgar scores as shown in table 11. All the neonates

requiring NICU admission had an abnormal CTG trace that was persisting for > 30 minutes duration. Hence we found that the increased duration of abnormal CTG trace increased the chances for a NICU admission (Table 11, 12).

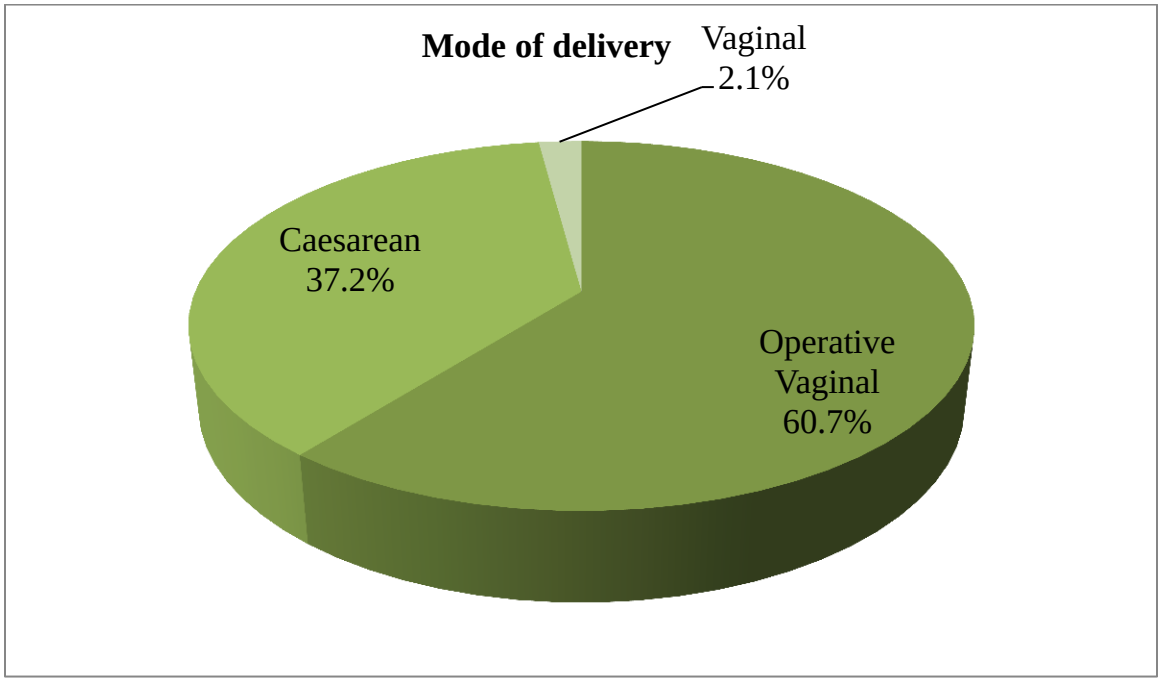


Figure 6: Mode of delivery among the women in this study

Among the study group 116(61%) women delivered by operative vaginal delivery which includes delivery either by suction cup or forceps. Caesarean section was done for 71(37.2%) women and 4 (2.1%) women delivered normally.

Table 15: Correlation between the CTG category and the mode of delivery

Mode of delivery	Mode of delivery			
	II	III	Total	
Caesarean	57(33.7%)	14(63.6%)	71(37.2%)	
Instrumental	108(63.9%)	8(36.4%)	116(60.7%)	P-value 0.03
Normal	4(2.4%)	0	4(2.1%)	
Total	169	22	191	

In this study we found that women who had category II CTG trace had more of an operative vaginal delivery108/169 (63.9%) followed by caesarean delivery 57/169 (33.7%). There were 4/169 (2.4%) women who delivered normally with a category II CTG. Among the women who had a category III CTG, 14/22 (63.6%) of them had a caesarean delivery and 8/22 (36.4%) had an operative vaginal delivery. There were no women in this category who delivered normally. Overall there was more chance for an

operative delivery among women with an abnormal CTG during labour which was statistically significant (p value 0.03).

DISCUSSION

Intrapartum fetal heart rate abnormalities occurring in presence of uterine contractions can be the reflection of placental circulation and fetal tissue perfusion. Intrapartum fetal surveillance can be done by various methods. Electronic fetal monitoring using cardiotocography (CTG) is a simple option available. The CTG trace was described according to NICHD 2008 classification. For identification of intrapartum asphyxia, sensitivity of this EFM was found to be 93% and positive predictive value was just 3-18%(30).

A study by Ray et al, found that the indeterminate (category II CTG) is seen in 36.5% of labouring women, abnormal (category III CTG) in 13.3% whereas the rest 50.2% of women had normal CTG finding described as category I trace (72). In the study by Jackson et al where all the women in labour were evaluated and he found 77.9% of women with category I CTG, 22.2% had category II CTG and only 0.004% with category III CTG (26). In this study we evaluated only women with abnormal CTG trace and found that of the 191 women in the study, 81.68% had a category II CTG and the remaining had a category III CTG.

In the study by Gupta et al abnormal CTG was correlated with Apgar score at 5 minute and the mode of delivery in such cases. He found a statistically significant higher number of women with non-reactive CTG who delivered babies with Apgar <7 at 5 minute. In their study the CTG was not categorized according to NICHD classification (73). In another study by Sunitha.C et al, which was a prospective case control study, they found significantly low Apgar scores at 1 minute in babies who had abnormal CTG trace (74).

In other studies done globally they found a similar result (75,76). In this study there was only 1% of the babies who had an Apgar of <7 at 5 minutes and it was not statistically significant (p value 1), unlike other studies done so far.

Cord blood gas is a simple measure of evaluating the degree of damage done to a neonate who is depressed at birth which further aids in focusing the management in prevention of neurological sequelae. There have been various studies done on this front and in the study by Ray et al, a cord pH of 7.2 was taken as a cut off where a neonate with a cord pH of <7.2 was labeled as being asphyxiated and hence given treatment in the neonatal intensive care unit (77). In the study by Larma et al, which was a case control study, they found that abnormal CTG patterns were associated with metabolic acidosis which were clinically correlated by a cord pH of <7(78). Another recent study by Soncini et al, also found that with worsening CTG trace, there was a statistically significant decrease in cord pH<7 (79). In this study there were 22 babies who had a cord pH done as they were depressed at birth. Of these 3 babies had a cord pH <7 with a very low incidence which was not statistically significant (p value 1). Of these 3 babies, 2 of them had category II CTG trace and one had category III CTG.

The babies who are depressed at birth usually are admitted in the NICU for monitoring and further evaluation of any sequelae to birth asphyxia.

In the study by Sunitha et al, out of total neonatal admissions to NICU 63.3% belonged to the group with abnormal CTG patterns and rest from normal patterns and it was not statistically significant (p-value 0.5) (74). A similar finding was seen in another study by Gupta et al (73). Amsumang et al, evaluated women who delivered in a tertiary care

centre in Thailand. In their study out of the 120 participants, only 5 babies required NICU admission and they found that the NICU admission rate between the normal and abnormal CTG patterns were not statistically significant (80).In this study there were 16 babies who were admitted in NICU as they were depressed at birth and required further specialized care. There were 40.9% (9/22) babies who had a category III CTG trace and 4.1% (7/169) babies had a category II CTG trace. We thus found that there was a statistically significant increase in admission to NICU with a category III CTG tracing (p value <0.0001).

There were various studies evaluating the correlation between CTG abnormalities and neonatal problems like hypoxic ischemic encephalopathy, respiratory distress syndrome, metabolic acidosis, sepsis, etc. Though there were Indian studies evaluating abnormal CTG and its correlation with various factors such as low Apgar, low cord pH and NICU admissions, these studies did not evaluate in detail about the various neonatal problems that the baby encountered during his/her stay in the hospital (74,77). In the study by Bagdanovic et al, which was a retrospective analysis of the CTG traces and Apgar score of neonates who were affected with HIE, found a statistically significant correlation between pathological CTG and the development of HIE. In their study they did not categorise the CTG according to the NICHD classification (76). In the case-control study by Larma et al, they found a significant increase in incidence of HIE and metabolic acidosis among babies who had an abnormal CTG trace (78). Similarly other studies have shown a positive correlation between abnormal CTG and adverse neonatal outcome. In our study we did not have a control group with normal CTG trace to compare the

correlation of an abnormal CTG with adverse neonatal outcome. However, we found that though the number of babies with HIE and metabolic acidosis was higher in the group who had a category III CTG than the ones with a category II CTG, it was not statistically significant (p value 0.627). This shows that a category II and III trace have an equal odd of developing neonatal problems which was not statistically significant.

There are various studies which have compared individual components of the CTG and its abnormalities to adverse neonatal outcome. Sunitha et al, found no association between absent beat to beat variability and low Apgar scores/NICU admission or the type of delivery (74). In the study by Amsumang et al, they found that in the univariate analysis, all the characteristics of the CTG i.e. minimal variability, baseline heart rate and variable decelerations were significantly associated with low Apgar scores and neonatal acidosis, but when the maternal age and gestational age was adjusted for, the association of the various components with Apgar scores was statistically insignificant whereas low cord pH was associated with minimal variability and any variable decelerations which was statistically significant (80). Larma et al found that the neonates with HIE had CTG that showed higher rates of bradycardia and decreased variability but no increase in late or variable decelerations. Though bradycardia and decreased variability were associated with HIE, their predictive values were low (78). In this study we found that poor variability was strongly associated with increased odds of the neonate being depressed at birth thus requiring NICU admission than a neonate who had a CTG trace with good variability (OR 7.54, 95% CI 1.53-37.21). We also looked into variable decelerations, both severe and non-severe, and their associations with the various

neonatal outcomes. We found that severe variable decelerations were not associated with low Apgar scores at 5 minutes but strongly associated with the neonate being depressed at birth thus requiring a cord blood gas for evaluation and subsequent NICU admission. There were 20.5% of babies who had severe variable decelerations in the CTG trace who were depressed at birth requiring a cord blood gas evaluation but only 4.4% of babies who had non severe decelerations required the same (p value 0.005). Similarly, there were 18.3% of neonates admitted in NICU who had severe variable decelerations and 5.3% who had non severe variable decelerations and the difference was statistically significant (p value 0.04). This was similar to the findings in the study by Amsumang et al(80).

Apart from the CTG category and its various components, the duration of abnormal CTG before delivery also had an association with adverse neonatal outcome as seen in various studies. In the study by Soncini et al, they found that a category III CTG lasting for a duration of 30 minutes or more was highly predictive of a cord pH <7 and similarly it 50 minutes for a category II trace (79). Other earlier studies also showed a similar finding. The Indian data did not look into the duration of the abnormal CTG before delivery. In this study, we had 178 (93%) CTG traces that were abnormal for more than 30 minutes and the remaining 13(7%) traces were abnormal for < 30 minutes before the woman delivered. We found that abnormal CTG traces for more than 30 minutes had higher odds of resulting in a neonate who was depressed at birth requiring NICU admission.

In the study by Sunitha et al. the association between non-reassuring CTG patterns and mode of delivery was observed, where 68% of women with abnormal CTG had operative

deliveries (P-value 0.000) (74). Gupta et al found a statistically significant increase chance of a caesarean delivery with an abnormal CTG compared with women who had a normal CTG during labour (p value <0.001)(73). In the another study by Roy et al, 6.8% women delivered by caesarean section due to non-reassuring CTG(28).

In this study 33.7% of women with category II delivered by LSCS, 63.9% delivered by operative vaginal delivery and 2.4% delivered normally. Among the women who had a category III CTG 63.6% of the women delivered by LSCS and 36.4% by operative vaginal delivery and no one delivered vaginally. Thus we saw that operative vaginal deliveries were more common with category II trace whereas women with category III CTG were more likely to have a caesarean delivery. Overall 37.2% of women had a caesarean section, 60.7% had an operative vaginal delivery and 2.1% had a normal delivery. Hence we found that there was statistically significant increase in operative deliveries (p value 0.03).

LIMITATIONS

- This is an observational study hence inter-observer and intra-observer bias cannot be ruled out.
- As this study was done in the tertiary care center with availability of CTG monitoring for all the patients and round the clock availability of operation theatre, this cannot be extrapolated to the medical centers where these facilities are not available.
- The cord pH was not done universally for all the babies, whose mothers were included in this study because of financial constraints. It was only done where neonates who required positive pressure ventilation as a resuscitative measure and had category III trace. For documentation and exact comparison cord pH would have been done for all neonates included in the study.
- This study did not include long term follow up therefore complications like poor school performance, mental retardation, cerebral palsy could not be commented upon.

CONCLUSION

Labour can be the state of progressive acidemia and fetus encounter physiological stress which can become pathological if intrapartum surveillance and timely delivery is not done.We studied that correlation between CTG category and requirement of extensive resuscitation and neonatal depression at birth.

- The possibility of depression at birth in case of category II and category III is comparable.
- Presence of reduced variability and/or severe variable decelerations irrespective of the category is independent risks of neonatal depression at birth (P-value 0.001 and 0.02 respectively). Presence of good variability is reassuring.
- The association of CTG category with low Apgar and cord pH<7 was not statistically significant (p value 1 for each), but the rate of NICU admission was higher in the category III CTG when compared to category II and it was statistically significant (p value <0.0001, 95% confidence interval 0.07-0.17).
- The association between the CTG category and various neonatal problems was statistically not significant (P-value 0.8).
- Poor variability and severe variable decelerations was associated with neonates who were depressed at birth and required NICU admission for further evaluation and management. This association was statistically significant (p value 0.006 and 0.005 respectively).

- Category III traces, increases the rate of caesarean deliveries whereas the chances of operative vaginal delivery is increased in presence of category II traces and the association is statistically significant (P- value 0.03).

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Information Sheet

Study title: A prospective observational study to identify the intrapartum fetal heart rate changes (continuous cardiotocography patterns) and the neonatal outcomes.

Aim of the study:

Intrapartum fetal distress diagnosed by CTG is sometimes an over diagnosis. It has led to increase in rate of Caesarean sections primarily for non-reassuring fetal heart rate in labour .Fetal blood sampling identifies the developing acidemia. Indeed it is a reliable method for excluding fetal as unlikely there is a false negative test result. Because of limited resources and facility in developing country like ours, we have to depend upon the CTG for fetal heart interpretation. Therefore there is need to know which are the CTG traces patterns which needs immediate intervention and on the other hand where we can wait.There is a grey zone in the three tier fetal heart rate interpretation system recommended by 2008 NICHD workshop that is the category II. These are the tracings where we have to take decision whether we can wait for some time or needs immediate delivery. In case we are waiting, how long we can give. Moreover the decision making is individualized in our institution. Hence by doing this study we will try to obtain more uniformity in trace interpretation. On the other hand balancing the rate of Caesarean sections and avoidance of neonatal depression.

The study will be done in labour room as patients will be recruited from there. The women in either spontaneous labour or the one with induced labour will be on continuous fetal heart rate monitoring. Those with heart rate tracings falling into category II will be recruited after the

informed consent. The investigator will not be taking the decision of delivery. It will be taken by the labour room team. Neonates will be followed at delivery and to nursery if they get admitted there. Newborn depression at birth will be identified by Apgar <7 at 5 min, abnormal breathing requiring Positive Pressure Ventilation, cord pH <7.2,base excess >12mmol/L,NICU admission and development of encephalopathy.

You are being requested to participate in a study to identify the fetal heart rate patterns during labour which leads to neonatal depression.

If you take part in this study what are you expected to do?

If you agree to participate in this study, your baby will be followed at delivery and after delivery for 6 weeks if required.

There will not be any deviation from the normal care which you are supposed to get in our labour room.

If any intervention is required at any time intrapartum, it will be taken. There will not be any delay at any condition just because you are a part of this study.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

Will your personal details be kept confidential?

Your identity will be kept confidential .It will not disclosed to the third party. But the outcome of this study may be used for publication purpose. The results of this study may

be published in a medical journal but you will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you develop any side effect or problem due to the study, this will be treated at no cost to you.

Will you be provided with any monetary compensation?

You will not be provided with any monetary compensation at any cost/condition.

If you have any further questions, please ask Dr. Minakshi Kumari (telephone/mobile no.: 04162283399/9655535481), email: og3@cmcvellore.ac.in

Name of Principal Investigator: Dr.Minakshi Kumari Contact no: 9655535481

INFORMED CONSENT

Study title: **Intrapartum Fetal Heart Rate Patterns (Fetal Distress) and Perinatal Outcome**

Study no.:

Subject's initials:_____ Subject's Name:_____

Age:

(i)I confirm that I have read and understood the information sheet dated _____for the above study and have had the opportunity to ask questions.[ ]

(ii)I understand that my participation in this study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii)I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or thumb impression) of the Subject/legally acceptable representative:

_____

Date: _____

Signatory's Name: _____

Signature of the investigator:_____

Date: _____

Name of the investigator: _____

Signature of the witness: _____

Date: _____

Name of witness: _____

Name of principal investigator: Dr.Minakshi Kumari

Contact no.: 9655535481

PROFORMA

1. Serial no.
2. Name
3. Age
4. Hospital no
5. Gestation age ____weeks __days
6. Gravida
7. Parity
8. Maternal risk factors
9. Labour onset Spontaneous / IOL
10. Indication for IOL
    - Postdate
    - IUGR
    - Oligohydramnios
    - Hypertensive Disorders in Pregnancy
    - GDM
    - Pre-gestational DM
    - Others
11. Method of IOL PGE1 / Foley / PGE1 + Foley
12. Colour of Liquor C / M / B
13. Augmentation Yes / No
14. NRFS Category I/ II/III

BHR	Normal	Tachycardia	Bradycardia	Indefinite
Variability	Good	Moderate	Poor	
Acceleration	Present	Absent		
Deceleration	Early	Variable	Late	

Variable → Severe / Non-severe

Duration of deceleration	<30min	>30min

15. Tachysystole Yes / No
16. Hyperstimulation Yes / No
17. Terbutaline (for fetal distress) Yes / No
18. Amnioinfusion Yes / No
19. Time of posting
20. Time of delivery of baby
21. Birth weight
22. Mode of delivery LSCS / Operative vaginal / NVD
23. Time required for resuscitation <1 min >1min
24. Apgar 5minutes
25. Cord pH done Yes / No
    pH >/= 7 <7

base excess _____

26. NICU admission for neonatal depression Yes / No
27. Number of days of NICU stay
28. Neonatal problems RDS/Metabolic/HIE (stages)

slno	age	gestage	gravida	parity	gdm	pregdm	ghtn	chronichtn	mpe	spe	advanage	hypothyr	anemia	shortstat	materoth	labour	indiiol	methodiol	color	augmen	nrfs	bhr
1	29	37.4	1	0	2	2	1	2	2	2	2	2	2	2	2	2	4	3	1	1	2	1
2	36	39.4	3	2	2	2	2	2	2	2	1	2	2	2	2	1			1	2	3	4
3	36	37.6	3	1	1	2	2	2	2	2	1	2	2	2	2	1			2	1	3	2
4	23	40	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	3	2
5	26	37	3	1	2	1	2	2	2	2	2	2	2	2	2	1			1	2	2	2
6	22	39.4	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	1	2	1
7	23	39.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
8	24	38.4	1	0	2	2	2	2	2	2	2	2	1	2	2	1			1	2	2	1
9	27	38.4	1	1	1	2	2	2	2	2	2	2	2	2		2	6	1	1	2	2	1
10	20	37.5	1	0	1	2	2	2	2	2	2	2	2	2	2	2	5	1	1	1	2	1
11	26	40.1	3	0	1	2	2	2	2	2	2	2	2	2	2	1			1	1	2	2
12	20	38	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	3	1	2	2	1
13	28	41	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	3	1	1	2	1
14	31	38	3	1	2	2	2	2	2	2	2	2	2	2	2	1			2	2	2	1
15	25	38.3	2	0	2	2	2	2	2	2	2	1	2	2	2	2	2	3	2	1	2	1
16	29	38	1	0	2	2	2	2	2	2	2	2	1	2	2	2	6	1	1	1	2	1
17	23	40.2	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1
18	38	38.6	3	2	2	2	2	1	2	2	2	2	2	2		2	4	3	2	1	2	1
19	24	40.3	1	0	2	2	2	2	2	2	2	2	2	2	1	2	1	1	1	1	2	1
20	24	40.4	1	0	1	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2	1
21	27	38.5	3	2	1	2	2	2	2	2	2	2	2	2	2	2	3	3	1	1	2	1
22	24	39.6	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	3	1	1	3	2
23	25	39.5	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1
24	23	39.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
25	25	40.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	3	1	1	2	4
26	30	38.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	2	2	4
27	30	39.6	1	0	2	2	1	2	2	2	2	2	2	2	2	2	4	3	1	1	2	1
28	21	39.4	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
29	29	40.5	1	0	1	2	2	2	2	2	2	2	2	2	1	2	1	1	1	1	2	1
30	26	39.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	2	2	1
31	32	40.4	3	1	2	2	2	2	2	2	2	1	2	2	2	2	1	1	1	1	2	2
32	26	38.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	3	1	1	2	1
33	23	38.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	3	1	1	1	2	1
34	17	38.1	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	2	2	1
35	26	38.2	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	2	2	4
36	28	39.5	1	0	2	2	2	2	2	2	2	1	2	2	2	1			2	1	2	2
37	27	37.3	1	0	2	2	1	2	2	2	2	2	2	2	2	2	4	1	1	1	2	2
38	20	39.2	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
39	30	39.2	2	1	1	2	2	2	1	2	2	2	2	2	2	2	5	3	1	1	2	1
40	32	38.5	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	3
41	24	39	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	3	2
42	31	38.3	1	0	2	1	2	2	2	2	2	2	2	2	2	2	5	1	1	1	2	1
43	24	39.2	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
44	24	38.5	1	0	1	2	2	2	2	2	2	2	2	2	2	2	5	3	2	1	2	1
45	22	39.2	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	2	2	1
46	24	37.2	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	2	1
47	31	37.2	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
48	22	38.3	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
49	26	38.1	2	0	1	2	1	2	2	2	2	1	2	2	2	2	4	3	2	2	3	1
50	26	38.6	1	0	2	2	2	2	2	2	2	2	1	2	2	1			1	1	2	2
51	29	40.2	1	0	1	2	2	2	2	2	2	2	2	2	2	2	1	3	1	1	2	4
52	33	40.1	1	0	2	2	2	2	2	2	1	2	2	2	2	2	6	3	2	1	2	2
53	22	39.3	1	0	2	2	2	2	2	2	2	1	2	2	2	2	6	1	2	1	2	2
54	26	40.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	2	1	2	1
55	25	39.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
56	28	40.2	2	1	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
57	21	38.6	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
58	22	39.6	1	0	2	2	2	2	2	2	2	2	2	2	2	2	3	1	1	1	2	1
59	28	38.5	2	1	1	2	2	2	2	2	2	2	2	2	2	2	5	1	1	1	2	1
60	23	37.2	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	3	1	1	2	1
61	27	40.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	2	1	2	2
62	20	40.3	2	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	2
63	24	38.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	3	2
64	34	37.5	3	1	1	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1

variab	accele	decele	variable	durdecel	nrtrace	tachys	hypersti	terbut	amnio	posttime	babytime	birthwt	delivery	timeresus	apgar	cordph	ph	base	nicu	nicustay	neonpblm	hiestages
2	1	2	2	2	2	2	2	2	2		23.51	2860	2	1	8	2	2	13.2	1	17	1	2
3	2	2	1	2	2	2	2	2	2		4.35	2620	2	2	9	1	2	10.3	1	16	1	2
3	2	2	1	2	2	2	1	2	2		17.15	2840	2	2	8	1	1	3.8	1	15		
3	1	4			2	1	2	1	2	19.2	20.18	2720	1	2	9	1	1	6.1	1	7		
3	2	2	1	2	2	2	2	2	2	4.5	5.1	2140	1		10	2			2			
1	1	2	2	2	2	2	2	2	1	14.25	15.45	2240	1	1	9	2			2			
1	2	2	2	2	2	2	2	2	2		17.3	2880	2		10	2						
1	2	3		2	2	2	2	2	2	2.3	3.13	2020	1	1	10	2			2			
3	1	2	1	2	2	2	2	2	1	22.3	0.14	2720	1	1	10	2			2			
1	1	1		2	2	2	2	2	2	12.45	13.2	3000	1	1	9	2			2			
1	1	1		2	2	2	2	2	2	3	5.26	3200	1	1	10	2			2			
3	2	2	2	2	2	2	2	2	2	8.1	9.25	2500	1	1	10	2			2			
3	2	2	2	2	2	2	1	1	2	13.2	14.55	2920	2	1	10	2			2			
2	2	2	1	2	2	2	2	2	2	13.3	14.1	2500	1	1	10	2			2			
1	1	2	2	2	2	2	2	2	2	7.25	8.23	1860	1	1	10	2			2			
1	1	2	2	2	2	2	2	2	2		21.31	2250	2	1	10	2			2			
2	1	2	2	2	2	2	2	2	2		17.48	2580	2	1	10	2			2			
3	2	1		2	2	2	2	2	2	13.5	14.28	2340	1	1	10	2			2			
2	2	2	2	2	2	2	2	2	2		11.25	3140	2	1	10	2			2			
3	1	2	2	2	2	2	2	2	1		17.4	3770	2	1	9	2			1	8	3	
2	1	2	2	2	2	2	2	2	1	17	17.36	2560	1	1	10	2			2			
3	2	2	2	2	2	2	1	2	2	2.3	3.15	2780	1	1	10	2			2			
1	1	2	2	2	2	2	1	1	1	14.1	15.05	3060	1	1	10	2			2			
2	2	2	1	2	2	2	2	2	2		17.3	2880	2	1	10	2			2			
1	2	3		2	2	2	2	2	2	6.2	7.5	3060	1	1	10	2			2			
1	2	2	2	2	2	2	1	1	1	20.5	21.25	2820	1	1	10	2			2			
2	1	2	2	2	2	2	1	2	1	1.4	2.2	3120	1	1	9	2			2			
2	2	2	1	2	2	2	2	2	2		18.12	2740	2	1	10	2			2			
1	2	2	2	2	2	2	1	1	1		9.15	3230	2	1	10	2			2			
1	1	2	2	2	2	2	1	2	2		4.34	2860	2	1	10	2			2			
2	2	2	1	2	2	2	1	1	2	23.45	0.07	3100	1	1	10	2			2			
1	1	2	2	2	2	2	2	2	2		18.09	2880	2	1	10	2			2			
1	1	2	2	2	2	2	2	1	2		12.48	2690	2	1	10	2			2			
1	2	2	2	1	1	2	1	2	2		15.05	2894	2	1	10	2			2			
2	2	2	2	2	2	2	2	2	2		23.15	2880	2	1	10	2			2			
2	2	2	1	2	2	2	2	2	2		5.47	3320	2	1	10	2			2			
2	2	2	1	2	2	1	2	2	2		9.18	2510	2	1	10	2			2			
2	2	2	2	2	2	2	2	2	2		22.49	3060	2	1	10	2			2			
2	1	2	2	2	2	2	2	2	2		21.3	2850	2	1	10	2			2			
2	2	4		1	1	2	2	2	2	20.2	21.09	3280	1	1	10	2			2			
2	2	2	1	2	2	2	2	2	2		4.36	3670	2	1	9	2			2			
1	1	2	2	2	2	2	1	2	2		12.43	3310	2	1	9	2			2			
2	1	2	2	2	2	2	1	2	2		12.27	2836	2	1	10	2			2			
1	1	2	2	2	2	2	2	1	1		15.56	3210	2	1	10	2			2			
1	1	2	2	2	2	2	1	2	2		3.19	2860	2	1	10	2			2			
1	1	2	2	2	2	2	1	2	2		21.38	2250	2	1	10	2			2			
1	1	2	2	2	2	2	1	2	2		12.16	3000	2	1	10	2			2			
2	1	2	2	1	1	2	2	2	2	12.15	12.52	2280	1	1	10	2			2			
3	2	3		2	2	2	2	2	2	9.2	9.42	3320	1	1	10	2			2			
3	2	2	1	2	2	2	2	2	2		22.3	3250	2	1	10	2			2			
2	1	3		2	2	2	2	2	2	13.15	13.5	2760	1	1	10	2			2			
2	1	2	2	2	2	2	2	2	2	18	18.55	2720	1	2	9	1	1	5.3	2			
2	1	4		2	2	2	2	2	2	19	19.35	3580	1	1	10	2			2			
3	1	2	2	2	2	2	2	2	2	19.3	20.21	2810	1	1	10	2			2			
1	1	2	1	2	2	1	2	1	1		14.41	2990	2	1	10	2			2			
1	1	2	2	2	2	2	2	2	2		11.4	3066	2	1	10				2			
1	1	2	2	2	2	2	2	2	2		19.17	3090	2	1	10	2			2			
1	1	2	2	2	2	2	2	2	2		19.36	2960	2	1	10	2			2			
1	2	2	1	2	2	2	2	2	1	21	21.44	3420	1	1	10	2			2			
3	2	1		2	2	2	2	2	2	11	12.24	2140	1	1	10	2			2			
2	1	2	2	2	2	2	1	2	2		16.36	3670	2	1	10	1	1	6.2	2	21	3	
2	1	2	1	2	2	2	2	2	2		16.4	3010	2	2	7	1	1	4.6	1	6	2	
3	2	3		2	2	2	1	2	2		17.02	2680	2	1	10	2			2			
2	2	2	2	2	2	2	1	2	2		10.34	2638	2	1	10	2			2			

65	24	39.3	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	2	2	1
66	27	40.1	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2	2
67	28	38.2	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1
68	29	40	1	0	2	2	2	2	2	2	2	1	2	2	2	1			2	1	2	1
69	24	40	2	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
70	19	38.5	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1
71	23	40.1	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
72	29	40	2	1	1	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
73	28	39.1	2	0	1	2	2	2	2	2	2	2	2	2	2	2	5	3	1	1	2	2
74	27	38.1	1	0	1	2	2	2	2	2	2	1	2	2	2	2	6	1	1	1	2	2
75	23	37.2	1	0	1	2	2	2	2	2	2	2	2	2	2	2	2	3	1	1	2	1
76	27	38.6	1	0	1	2	2	2	2	2	2	2	2	2	2	2	6	3	2	1	2	2
77	18	40	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	2
78	20	39.5	1	0	2	2	2	1	2	2	2	2	2	2	2	2	2	3	2	1	2	1
79	29	40	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
80	25	39.5	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	2
81	39	38.4	1	0	2	2	2	2	2	2	1	2	2	2	2	1			1	1	2	1
82	23	40.2	1	0	1	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2	1
83	27	39.4	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	3	1	1	3	2
84	22	39.4	2	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1
85	28	40	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2	3
86	20	40.2	1	0	2	2	1	2	2	2	2	2	2	2	2	2	1	1	2	1	2	1
87	25	40.4	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2	2
88	22	39.6	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	1	2	2	2	2
89	27	40	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	1	1	1	2	1
90	34	38.3	1	0	2	2	2	2	2	1	1	2	2	2	2	2	4	3	1	1	2	1
91	24	39.1	1	0	2	2	1	2	2	2	2	2	2	2	2	2	4	1	1	1	3	1
92	26	39.4	1	0	2	2	2	2	2	2	2	2	2	1	2	1			1	1	2	1
93	22	39.5	1	0	2	2	2	2	2	2	2	2	2	2	2	1			2	1	2	1
94	32	39.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	6	2	1	1	2	1
95	27	38.3	1	0	2	2	2	2	2	2	2	2	2	2	1	2	6	1	1	1	2	2
96	23	37.4	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	2	2	1
97	27	40	2	1	2	2	2	2	2	2	2	1	2	2	2	1			2	1	3	2
98	25	40.2	1	0	2	2	1	2	2	2	2	2	2	2	2	2	4	1	2	1	2	1
99	24	40.4	1	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	1	1	2	2
100	25	37	2	0	2	2	2	2	2	2	2	2	2	2	2	2	2	3	1	1	3	2
101	21	38.3	1	0	2	2	2	2	2	2	2	2	2	2	2	2	2	2	1	1	2	2
102	28	39.2	1	0	2	2	2	2	2	2	2	2	2	2	2	1			1	1	2	1
103	35	37.4	1	0	2	2	2	2	2	2	1	2	2	2	2	1				2	2	1
104	25	40.3	2	0	2	2	2	2	2	2	2	2	2	2	2	2	1	1	2	1	2	1
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2	1	2	2	2	2	2	1	2	2		5.31	2800	2	1	10	2			2			
2	1	3		2	2	2	2	2	2	10.4	11.27	2860	1	1	9	2			2			
2	2	2	1	2	2	1	1	2	2		12.16	3120	2	1	9	2			2			
1	2	3		2	2	2	2	2	2		6.13	3430	2	1	9	2			2			
3	2	4		2	2	2	2	2	2	4.15	4.5	2440	1	1	9	2			2			
2	1	2	2	2	2	2	1	2	2		14.06	2330	2	1	10	2			2			
2	2	2	2	2	2	2	2	2	2		14.48	2310	2	1	9	2			2			
2	1	2	1	2	2	2	2	2	2		19.3	2720	2	1	10	2			2			
3	2	3		2	2	2	2	2	2	6.2	6.4	2800	1	2	9	1	1	11.7	2			
2	1	3		2	2	2	2	2	2	11.1	12.17	3240	1	1	10	2			2			
2	1	3		2	2	2	2	2	1	22.3	23.05	2940	1	1	10	2			2			
3	1	2	2	2	2	2	2	2	2	9.1	9.56	2740	1	1	10	2			2			
2	1	4		1	1	1	1	1	2		11	2830	2	1	10	2			2			
2	1	2	2	2	2	2	2	2	2		2.56	2900	3	1	10	2			2			
2	2	2	1	2	2	2	2	2	2		7.16	3470	3	1	10	2			2			
2	1	2	2	2	2	2	2	2	2	5.05	5.25	3080	1	1	10	2			2			
1	2	3		2	2	2	1	2	2	17.15	17.56	3580	1	2	10	1	1	6.4	2			
2	1	2	2	2	2	2	1	2	1		7.5	3100	2	1	10	2			2			
3	2	2	1	2	2	2	1	2	2		0.13	2580	2	2	9	1	1	16.4	1	5	2	
2	2	2	1	2	2	2	2	2	1	1.26	2.15	3280	1	2	10	1	1	6.4	2			
3	1	2	1	2	2	2	1	2	2		20.2	2470	2	1	10	2			2			
2	2	2	2	2	2	1	1	2	2		17.43	3320	2	1	9	2			2			
1	2	2	2	2	2	1	1	2	2		1.4	2750	2	1	10	2			2			
3	2	3		2	2	2	2	2	2	14	14.23	3180	1	2	9	1	1	8.8	1	5		
3	2	2	2	2	2	2	1	2	1	22	22.48	2980	1	2	9	1	1	16.2	1	4		
2	1	2	2	2	2	2	1	1	2		19.39	2510	2	1	10	2			2			
2	1	2	2	2	2	2	2	2	2		10.4	3290	2	1	10	2			2			
2	2	2	2	2	2	1	2	2	2		1.4	2750	2	1	10	2			2			
2	2	2	2	2	2	1	2	2	2		8.54	3200	2	1	10	2			2			
2	1	2	2	2	2	2	1	2	2		11.11	3300	2	1	10	2			2			
2	1	2	2	2	2	2	1	2	2		11.43	2700	2	1	10	2			2			
2	1	2	2	1	1	2	2	2	2		13.54	2430	2	1	10	2			2			
2	2	2	1	2	2	2	2	2	2	18.4	19.19	2420	1	2	8	1	1	5	1	9	2	
3	2	2	2	2	2	1	1	2	2	18.05	18.2	2000	1	2	8	1	1	10.3	1	6	2	

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

May 01, 2017

Dr. Minakshi Kumari,
PG Registrar,
Department of OG -3,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**
Intrapartum Fetal Heart Rate Patterns (Fetal Distress) and Perinatal Outcome. Minakshi Kumari, Employment Number:21128, P G Registrar, O & G, Unit III, Dr Annie Regi, Professor, HOD, Employment Number:11190, Dr Anuja Abraham, Associate Prof, Employment no.31916, Dr Santhanam Sridhar, Professor, Employment no.30531 Ms. Reka.K, Senior demonstrator, Employment no.32547, Department of Statistics.

Ref: IRB Min. No. 10418 dated 05.12.2016

Dear Dr. Minakshi Kumari,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

CC: Dr Annie Regi, OG - 3, CMC

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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Ref: IRB Min. No. 10418 (OBSERVE) dated 05.12.2016

Dear Dr. Minakshi Kumari,

The Institutional Review Board (**Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Intrapartum Fetal Heart Rate Patterns (Fetal Distress) and Perinatal Outcome" on December 05th 2016.

The Committee reviewed the following documents:

1. IRB Application format
2. Proforma
3. Information Sheet and Informed Consent Form (English and Tamil)
4. Cv of Dr. Annie Regi.
5. No. of documents 1- 4

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

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Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 05th 2016 in the BRTC Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC,Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA (Theology), Dr. Min (Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Dr. Ratna Prabha	MBBS, MD (Pharma)	Associate Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Dr. Rekha Pai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal,Basic Medical Scientist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Simon Pavamani	MBBS, MD	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Rajesh Kannangai	MD, PhD.	Professor, Clinical Virology, CMC, Vellore	Internal, Clinician
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician

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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. Santhanam Sridhar	MBBS, DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of withdrawals for the study entitled: "Intrapartum Fetal Heart Rate Patterns (Fetal Distress) and Perinatal Outcome" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 13,800/- INR (Rupees Thirteen thousand Eight Hundred Only) will be granted for 12 months.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 10418 (OBSERVE) dated 05.12.2016